To: Mike Kaplan <Mike.Kaplan@USA.dupont.com> Rose Allison/DC/USEPA/US@EPA
From: Jane Bradd Andersen <JANE-BRADD.ANDERSEN@usa.dupont.com>
Cc: James R Hoover <James.R.Hoover@USA.dupont.com>
Subject: Re: TSCA 8e Letter - P-08-509
Submit Time: 2/23/2010 13:41:29

Mike,
Thank you so much.
Kind regards,
Jane
sent from my Blackberry Wireless Handheld

----- Original Message -----
From: Mike Kaplan
Sent: 02/23/2010 08:36 AM EST
To: allison.rose@epamail.epa.gov
Cc: Jane Bradd Andersen; James R Hoover; Mike Kaplan
Subject: TSCA 8e Letter - P-08-509

Dear Rose Allison,

Per Jane Bradd Andersen's request, attached is a copy of the letter for P-08-509.

Sincerely,

Mike

A.Michael Kaplan, Ph.D.
Director - Regulatory Affairs
DuPont Haskell Global Centers for Health & Environmental Sciences
1090 Elkton Road
P.O. Box 50
Newark, DE 19714
302-366-5260 Phone
302-451-4531 Fax
mike.kaplan@usa.dupont.com

[attachment "2-5-10 FRD-902 2010-033 Letter.pdf" deleted by Jane Bradd Andersen/AE/DuPont]

From: James R Hoover <James.R.Hoover@USA.dupont.com>
To: Rose Allison/DC/USEPA/US@EPA
Subject: Fw: URGENT ISSUE: 18405-1037 mouse study blood collection amendment -
Submit Time: 4/30/2010 21:56:39

Hi Rose...My sincere apologies if I did the wrong things here, but with Jane on vacation and out of communication until may 10, I tried my best to see what options we actually had late on a Friday afternoon.

This is clearly our mistake, and I take full responsibility for it. I also fully realize this may be difficult to impossible on such short notice, but I wanted to make fully sure that what ever we do (and I did) was totally right.

So, please call on Monday if you have any questions, or if there is something else I need to do. Thx.

Very best regards....Jim

Jim Hoover, FPS Global Regulatory Manager

DuPONT DCF/FPS
CRP 702, Room 2116
Wilmington, DE 19880

BBerry: Personal Phone / Ex. 6

----- Forwarded by James R Hoover/AE/DuPont on 04/30/2010 05:48 PM -----

James R Hoover/AE/DuPont

04/30/2010 04:16 PM

To seed.jennifer@epa.gov

cc

Subject: Fw: URGENT ISSUE: 18405-1037 mouse study blood collection amendment -

Jennifer....Greg Schweer directed me to Jim Allwood, and Jim told me to foward this EMail and give you a quick call, so I will call in a minute. May apologies for this,best rgds, Jim

----- Forwarded by James R Hoover/AE/DuPont on 04/30/2010 04:14 PM -----

James R Hoover/AE/DuPont

04/30/2010 03:57 PM

To schweer.greg@epa.gov

cc

Sub Fw: URGENT ISSUE: 18405-1037 mouse study blood
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For us to proceed as indicated, I think we would need a "non-objection" Email from EPA relative to this EMail before 6:00am this coming Monday morning (May 3rd).

The details are show below.

Any advice would be much appreciated. We fully realize this may be difficult to impossible, but I wanted to make fully sure that what ever we do is totally right.

Again, my apologies.

Very best regards, Jim

Jim Hoover, FPS Global Regulatory Manager

DuPONT DCF/FPS
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04/30/2010 03:11 PM

To Allison.Rose@epamail.epa.gov

cc Gary W Jepson/AE/DuPont@DuPont, Steven R Frame/AE/DuPont@DuPont, Susan M Munley/AE/DuPont@DuPont, Jane Bradd Andersen/AE/DuPont@DuPont

Subject Fw: URGENT ISSUE: 18405-1037 mouse study blood collection amendment -

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The details are outlined in the Notes from Randy Frame and Sue Munley, shown below.

Given the circumstances and timing, what options do we have to proceed, with EPA agreement, for what Randy and Sue recommend (i.e. a non-objection to proceed).

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Many thx for your advice...best regards, Jim

Jim Hoover, FPS Global Regulatory Manager

DuPONT DCF/FPS
CRP 702, Room 2116
Wilmington, DE 19880

BBerry: Personal Phone / Ex. 6

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Steven R Frame/AE/DuPont

04/30/2010 11:46 AM

To James R Hoover/AE/DuPont@DuPont, Jane Bradd Andersen/AE/DuPont@DuPont

cc Gary W Jepson/AE/DuPont@DuPont, Susan M Munley/AE/DuPont@DuPont

Subject URGENT ISSUE: 18405-1037 mouse study blood collection amendment -

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Randy

----- Forwarded by Steven R Frame/AE/DuPont on 04/30/2010 11:38 AM -----

Susan M Munley/AE/DuPont

04/30/2010 11:37 AM

To Steven R Frame/AE/DuPont@DuPont, Gary W Jepson/AE/DuPont@DuPont

cc

Subject 18405-1037 mouse study blood collection amendment - URGENT ISSUE

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We cannot obtain enough volume for this work without making the bleed a terminal bleed.

Therefore, we need to write another amendment (draft attached below) to specify that animals will be administered a single additional dose on the morning of scheduled euthanasia and then euthanized two hours following that dose.

I am writing to seek non-objection to proceed with this beginning this coming Monday morning, May 3.

The first F0 females to reach PND 21 are scheduled to have their litters weaned and be subsequently euthanized this coming Monday morning.

As these procedures will clarify and improve upon the data dictated by the previously approved amendment 4, please let me know if we can proceed with approving this work to begin on Monday.

189225 Draft Amendment 5 043010.doc 

DuPont Haskell Global Centers
for Health and Environmental Sciences
1090 Elkton Road, P.O. Box 50
Newark, DE 19714-0050

February 5, 2010

Via Federal Express

Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency, ICC Building
1201 Constitution Ave., NW
Washington, DC 20004

Dear 8(e) Coordinator:

PBI / Ex. 4

This letter is to inform you of the preliminary results of a developmental toxicity study in rats with the above referenced test substance. This test substance is subject to a Consent Order, PMN P-08-509.

Groups of 22 time-mated Crl:CD(SD) rats were administered solutions of the test substance in deionized water at dose levels of 0, 10, 100, or 1000 mg/kg/day. Dosing was initiated on gestation day (GD) 6 and continued through GD 20. During the in-life portion of the study, maternal body weights and food consumption as well as clinical observations data were collected. On GD 21, dams were euthanized and underwent a gross external and internal examination. Weights for maternal livers and kidneys were recorded and these tissues were preserved for future histopathologic examination. The gravid uteri were removed, weighed, and dissected. Uterine contents were described and fetuses were counted, weighed, sexed, and examined for external, visceral, head, and skeletal alterations.

PBI / Ex. 4

This information is submitted in accordance with current guidance issued by EPA indicating EPA's interpretation of Section 8(e) of the Toxic Substances Control Act or, where it is not clear that reporting criteria have been met, it is submitted as a precautionary measure and because it is information in which EPA may have an interest.

Sincerely,

A. Michael Kaplan/clp

A. Michael Kaplan, Ph.D.
Director - Regulatory Affairs

AMK/SMM: clp
(302) 366-5260

Subject: Fw: Re: Fw: URGENT ISSUE: 18405-1037 mouse study blood collection amendment -
From: CN=Greg Schweer/OU=DC/O=USEPA/C=US
To: CN=Rose Allison/OU=DC/O=USEPA/C=US@EPA
Cc:
Submit Time: 5/3/2010 18:51:10

FYI

Greg Schweer
Chief, New Chemicals Management Branch
Chemical Control Division
U.S. EPA, Office of Pollution Prevention and Toxics
(202)564-8469

-----Forwarded by Greg Schweer/DC/USEPA/US on 05/03/2010 02:50PM -----

To: Jennifer Seed/DC/USEPA/US@EPA
From: James R Hoover <James.R.Hoover@USA.dupont.com>
Date: 05/03/2010 01:47PM
cc: Greg Schweer/DC/USEPA/US@EPA
Subject: Re: Fw: URGENT ISSUE: 18405-1037 mouse study blood collection amendment -

Jennifer,

Again many thanks, and sorry for the last-minute inconvenience last Friday and today. I think that we did get the message in time this morning to make the needed revisions. Very best regards, Jim

Seed.Jennifer@epamail.epa.gov
05/03/2010 09:10 AM

To James R Hoover/AE/DuPont@DuPont

cc Schweer.Greg@epamail.epa.gov

Subject Re: Fw: URGENT ISSUE: 18405-1037 mouse study blood collection amendment -

Jim,

Sorry about the confusion over this. The protocol is fine. I hope you get this message in time.

Jennifer

Jennifer Seed, PhD
Deputy Director

Risk Assessment Division, OPPT
202-564-7634
seed.jennifer@epa.gov

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| From: |
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|James R Hoover <James.R.Hoover@USA.dupont.com>
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| To: |
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|Jennifer Seed/DC/USEPA/US@EPA
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| Date: |
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|04/30/2010 04:16 PM |
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To
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Again, my apologies.

Very best regards, Jim

Jim Hoover, FPS Global Regulatory Manager

DuPONT DCF/FPS
CRP 702, Room 2116
Wilmington, DE 19880

BBerry: Personal Phone / Ex. 6

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cc: Gary W Jepson/AE/DuPont@DuPont, Steven R Frame/AE/DuPont@DuPont, Susan M Munley/AE/DuPont@DuPont, Jane Bradd Andersen/AE/DuPont@DuPont

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cc
Gary W Jepson/AE/DuPont@DuPont, Susan M Munley/AE/DuPont@DuPont

Subject
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Susan M
Munley/AE/DuPont

To
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cc

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As these procedures will clarify and improve upon the data dictated by the previously approved amendment 4, please let me know if we can proceed with approving this work to begin on Monday.

(See attached file: 189225 Draft Amendment 5 043010.doc)

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Francais Deutsch Italiano Espanol Portugues Japanese Chinese Korean

http://www.DuPont.com/corp/email_disclaimer.html

189225 Draft Amendment 5 043010.doc

Submit Time: 7/2/2010 16:26:21
From: CN=Rose Allison/OU=DC/O=USEPA/C=US
To: Jane Bradd Andersen <JANE-BRADD.ANDERSEN@usa.dupont.com>
Cc:
Subject: Re another topic and: Modified 1-generation Reproduction Study [OPPTS 870.3550] - another amendment

Jane, is this it ? I also need to talk to you about the respirator approval request. if you're in today, please call.

Rose Allison
Team Leader
New Chemicals Program
Chemical Control Division (7405M)
US EPA
1200 Pennsylvania Ave. NW
Washington, DC 20460
202/564-8970/FAX 202/564-9490

For Deliveries
EPA East Building
*1201 Constitution Ave NW *
Room 4419G
Wash DC 20004

Jane Bradd Andersen ---06/30/2010 03:33:51 PM---Dear Rose, In addition to the protocol modifications I sent on June 8, 2010, DuPont

From: Jane Bradd Andersen <JANE-BRADD.ANDERSEN@usa.dupont.com>

To: Rose Allison/DC/USEPA/US@EPA

Date: 06/30/2010 03:33 PM

Subject: Modified 1-generation Reproduction Study [OPPTS 870.3550] - another amendment

---

Dear Rose,

In addition to the protocol modifications I sent on June 8, 2010, DuPont requests approval for an additional modification not covered in the June 6,2010 email.

Briefly, this amendment will allow DuPont to perform the necessary statistical analyses on the developmental landmark data from the modified mouse one-generation reproduction study. DuPont would like to perform these analyses so that DuPont can complete the interpretation of these data as soon as possible.

It would be greatly appreciated if the Agency could expedite the review and approval of the protocol modifications so that DuPont can proceed.

Kind regards,

Jane Bradd-Andersen
tel:302-999-2377
fax:302-999-2177
jane-bradd.andersen@usa.dupont.com

Jane Bradd Andersen/AE/DuPont

To Allison.Rose@epamail.epa.gov

06/08/2010 10:29 AM

cc

Subject Modified 1-generation Reproduction Study [OPPTS 870.3550]

Dear Rose:

As a follow up to our conversation from Tuesday, June 1, 2010..... I am submitting for Agency approval modifications to the protocol for Modified One-Generation Reproduction Study in Mice. This protocol was initially approved by the Agency on November 2009. The Agency provided approval for Amendment 4 on April 28, 2010 and Amendment 5 on May 3, 2010 [see attached emails]. DuPont recognized other changes have occurred to the protocol subsequent to the initial Agency approval.

With this email I am requesting Agency approval for Amendments 1 through 3 to the protocol for Modified One-Generation Reproduction Study in Mice.

The following document is a copy of the protocol where the changes are embedded and highlighted using "track changes" tool for Microsoft Word.

The following is a copy of the protocol and changes as per the process employed by DuPont to satisfy GLP requirements.

Kind regards,

Jane Bradd-Andersen
tel:302-999-2377
fax:302-999-2177
jane-bradd.andersen@usa.dupont.com

********** ***AMENDMENT 4 APPROVAL*** **********

Allison.Rose@epamail.epa.gov

To Jane Bradd Andersen/AE/DuPont@DuPont

04/28/2010 01:35 PM

cc

Subject Re: April 7, 2010 Meeting request item

Hi Jane, Yes, OPPT/EPA approves the amendment. Rose

Rose Allison
Team Leader
New Chemicals Program
Chemical Control Division (7405M)
US EPA
20004**
1200 Pennsylvania Ave. NW
Washington, DC 20460
202/564-8970/FAX 202/564-9490

For Deliveries
EPA East Building
*1201 Constitution Ave NW *
Room 4419G
**Wash DC

From: Jane Bradd Andersen <JANE-BRADD.ANDERSEN@usa.dupont.com>

To: Rose Allison/DC/USEPA/US@EPA

Date: 04/26/2010 06:18 PM

Subject: April 7, 2010 Meeting request item

Hi Rose,

At the April 7, 2010 meeting with representatives from DuPont and the Agency, it was suggested that DuPont include plasma sample collection and analysis as part of the Modified one-Generation Reproduction study [OECD 421, modified] which was approved by the Agency on January 29, 2010. This subject was again discussed during the subsequent conference call on April 22, 2010 between representatives from DuPont and the Agency.

Can you please confirm Agency approval with the proposed amendment to the study? I have attached a copy of the proposal submitted to the Agency on April 14, 2010.

Kind regards,

Jane Bradd-Andersen
tel:302-999-2377
fax:302-999-2177

jane-bradd.andersen@usa.dupont.com

[attachment "189225 Draft Amendment 4 041210.doc" deleted by Rose Allison/DC/USEPA/US]

***********AMENDMENT 5 APPROVAL*** **********

Seed.Jennifer@epamail.epa.gov

To James R Hoover/AE/DuPont@DuPont

05/03/2010 09:10 AM

cc Schweer.Greg@epamail.epa.gov

Subject Re: Fw: URGENT ISSUE: 18405-1037 mouse study blood collection amendment -

Jim,

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Jennifer

Jennifer Seed, PhD
Deputy Director
Risk Assessment Division, OPPT
202-564-7634
seed.jennifer@epa.gov

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| From: |
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|James R Hoover <James.R.Hoover@USA.dupont.com>
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| To: |
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DuPONT DCF/FPS
CRP 702, Room 2116
Wilmington, DE 19880

BBerry: **Personal Phone / Ex. 6**

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CRP 702, Room 2116
Wilmington, DE 19880

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Munley/AE/DuPont

To
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As these procedures will clarify and improve upon the data dictated by the previously approved amendment 4, please let me know if we can proceed with approving this work to begin on Monday.

(See attached file: 189225 Draft Amendment 5 043010.doc)

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[attachment "18405-1037 protocol with amendments as tracked changes smm june 3,

2010.pdf" deleted by Rose Allison/DC/USEPA/US] [attachment "18405-1037 complete protocol smm 19 may 2010.pdf" deleted by Rose Allison/DC/USEPA/US] [attachment "189225 Draft Amendment 5 043010.doc" deleted by Rose Allison/DC/USEPA/US] [attachment "18405-1037 189225 Draft Amendment 6 smm 6-30-2010.doc" deleted by Rose Allison/DC/USEPA/US]

Submit Time: 4/7/2010 13:57:45
From: CN=Rose Allison/OU=DC/O=USEPA/C=US
To: CN=Anna Coutlakis/OU=DC/O=USEPA/C=US@EPA
Cc:
Subject: Fw: Mtg to discuss 8(e) letter contents

As we discussed...

Rose Allison

----- Forwarded by Rose Allison/DC/USEPA/US on 04/07/2010 09:57 AM -----

From: Rose Allison/DC/USEPA/US

To: Jennifer Seed/DC/USEPA/US@EPA, Rebecca Jones/DC/USEPA/US@EPA, Steven Cragg/DC/USEPA/US@EPA, Jim Willis/DC/USEPA/US@EPA

Cc: Oscar Hernandez/DC/USEPA/US@EPA, Toni Krasnic/DC/USEPA/US@EPA, Laurence Libelo/DC/USEPA/US@EPA, Greg Fritz/DC/USEPA/US@EPA, Bob Morcock/DC/USEPA/US@EPA, Sara Pollack/DC/USEPA/US@EPA

Date: 04/06/2010 03:39 PM

Subject: Fw: Mtg to discuss 8(e) letter contents

P08-509 8(e).pdf P08-509 8(e).pdf
Above is the 8(e) submission from DuPont. This is not a study required under the Consent Order but is a study that they are doing for other authorities. They are required to do a modified one-generation study in the Consent Order as well as a Pharmacokinetics study, 90-day toxicity study and the Chronic toxicity/carcinogenicity study at certain production volumes or time. Below please find the proposed agenda. This meeting will be tomorrow @ 11:00 am in 4140 and was requested by DuPont. Rose

---

Rose Allison
Team Leader
New Chemicals Program
Chemical Control Division (7405M)
US EPA
202/564-8970/FAX 202/564-9490

For Deliveries
EPA East Building
*1201 Constitution Ave NW
Room 4419H
Wash DC 20004

----- Forwarded by Rose Allison/DC/USEPA/US on 04/06/2010 03:16 PM -----

From: Jane Bradd Andersen <JANE-BRADD.ANDERSEN@usa.dupont.com>

To: Rose Allison/DC/USEPA/US@EPA

Date: 03/25/2010 09:05 AM

Subject: Re: Fw: Mtg to discuss 8(e) letter contents

Rose,

Here's the proposed agenda

1) Review study data for 8(e) letter and discuss pathforward.
2) Review Rat & Mouse 90 Day data, update of ongoing studies (modified one gen) & discuss species selection for 2 year study

Kind regards,

Jane Bradd-Andersen
tel:302-999-2377
fax:302-999-2177
jane-bradd.andersen@usa.dupont.com

Allison.Rose@epamail.epa.gov

03/18/2010 11:35 AM

To: Jane Bradd Andersen/AE/DuPont@DuPont

cc:

Subject: Re: Fw: Mtg to discuss 8(e) letter contents

PROTOCOL

AN ORAL (GAVAGE) REPRODUCTION/DEVELOPMENTAL TOXICITY SCREENING STUDY OF H-28548 IN MICE

(U.S. EPA OPPTS 870.3550 and OECD Guideline 421)

Submitted To:

E.I. du Pont de Nemours and Company
Wilmington, Delaware 19898

DuPont Work Request Number: 18405
DuPont Service Code: 1037
DuPont Study Number: 18405-1037

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-8946

1 OBJECTIVE:

To provide preliminary information on the potential adverse effects of the test substance on male and female reproduction within the scope of a screening study. This will encompass gonadal function, mating behavior, conception, parturition and lactation of the F_0 generation and the development of offspring from conception through day 40 of postnatal life.

This study is subject to the applicable regulations of the Organisation for Economic Cooperation and Development (OECD) Guideline for Testing of Chemicals, Guideline 421, Reproduction/Development Toxicity Screening Test, July 27, 1995, and the United States Environmental Protection Agency (EPA) Health Effects Test Guidelines OPPTS 870.3550, Reproduction/Developmental Toxicity Screening Test, July 2000 and will be conducted in accordance with the EPA/TSCA and FIFRA (40 CFR Part 792 and 40 CFR Part 160) and the OECD Principles of Good Laboratory Practice.

2 PERSONNEL INVOLVED IN THE STUDY:

2.1 Study Representative:

Susan M. Munley, MA
Research Toxicologist
Developmental, Reproductive and Neurobehavioral Toxicology
DuPont Haskell Laboratory for Health and Environmental Sciences
1090 Elkton Rd., PO Box 50
Newark, DE 19714
Tel: (302) 366-5240
Email: susan.m.munley@usa.dupont.com

2.2 Principal Investigator, Pathology

Greg P. Sykes, VMD, DACVP, DACLAM, DABT
PharmPath, LLC.
105 Phillips Mill Rd.
West Grove, PA, 19390-9165
Tel: (302) 451-3551
Cellular Tel: (484) 678-4433
Email: greg.p.sykes@usa.dupont.com

2.3 **WIL Study Director:**

Tammye L. Edwards, BS, LAT
Staff Toxicologist, Developmental and Reproductive Toxicology
WIL Research Laboratories, LLC
1407 George Road
Ashland, Ohio 44805
Tel: (419) 289-8700 ext. 2105
Fax: (419) 289-3650
Email: tledwards@wilresearch.com

2.4 **WIL Departmental Responsibilities:**

Eddie D. Sloter, PhD
Senior Toxicologist, Developmental
and Reproductive Toxicology
Emergency Contact
Tel: (419) 289-8700
Fax: (419) 289-3650
Email: esloter@wilresearch.com

Mark D. Nemec, BS, DABT
President and Chief Operating Officer

Donald G. Stump, PhD, DABT
Director, Developmental and
Reproductive Toxicology

George A. Parker, DVM, PhD, DACVP, DABT
Director, Pathology

Melissa J. Beck, PhD
Assistant Director, Neurosciences

Daniel W. Sved, PhD
Director, Metabolism and Analytical Chemistry

Walter R. Miller, BS, DVM
Clinical Veterinarian,
Head of Surgery and Experimental Medicine

Ronald E. Wilson, BS
Director, Informational Systems

Carol A. Kopp, BS, LAT
Manager, Gross Pathology and
Developmental Toxicology Laboratory

Heather L. Johnson, BS, RQAP-GLP
Manager, Quality Assurance

Bennett J. Varsho, MPH, DABT
Operations Manager, Developmental and
Reproductive Toxicology and the Formulations Laboratory

Robert A. Wally, BS, RAC
Manager, Reporting and Regulatory
Technical Services

3 STUDY SCHEDULE:

Proposed Experimental Starting (Animal Receipt) Date:	5 January 2010
Proposed Experimental Start (First Day of Dosing) Date:	14 January 2010
Proposed Experimental Completion/Termination Date:	4 June 2010
Proposed Audited Report Date:	To be determined

4 TEST SUBSTANCE DATA:

4.1 Test Substance Shipment:

Test substance and applicable documentation, including a Certificate of Analysis, will be shipped under Sponsor's responsibility to:

Formulations Laboratory (WIL-189225; Tammye Edwards)
Attn: Larry Blessing
WIL Research Laboratories, LLC
1407 George Road
Ashland, Ohio 44805-8946

4.2 Identification:

H-28548 or HFPO Dimer Acid Ammonium Salt

4.3 **Haskell Test Substance Number:**

H-28548

4.4 **Lot Number:**

E109540-44A

4.5 **Expiration/Retest Date:**

13 June 2011

4.6 **Purity:**

84%

4.7 **Storage Conditions:**

Controlled room temperature and humidity (approximately 18° to 24°C and 20% to 70% relative humidity)

4.8 **Stability:**

The analysis was performed by the Sponsor and documented on the Certificate of Analysis.

4.9 **Physical Description:**

To be documented by WIL Research Laboratories, LLC.

4.10 **Reserve Samples:**

Reserve samples of the test substance will be taken in accordance with WIL Standard Operating Procedures and stored in the Archives at WIL Research Laboratories, LLC indefinitely, unless otherwise specified.

4.11 **Personnel Safety Data:**

See the Material Safety Data Sheet (MSDS) provided by the Sponsor.

4.12 **Test Substance Disposition:**

With the exception of the reserve sample for each batch of test substance, which will be archived as described, all neat test substance remaining at completion of the in-life phase of the study will be kept for subsequent studies.

5 TEST SYSTEM:

5.1 Species:

Mouse

5.2 Strain:

Charles River Crl:CD1(ICR)

5.3 Source:

Males: Charles River Laboratories, Inc., Raleigh, NC
Females: Charles River Laboratories, Inc., Kingston, NY

5.4 Number on Study:

100 males and 100 females (minimum of 120 males and 120 females purchased; males and females will be ordered from separate facilities to ensure the avoidance of sibling mating). Animals not assigned to study will be transferred to the stock animal colony or will be euthanized by carbon dioxide inhalation and the carcasses discarded.

The number of animals used on this study is consistent with OPPTS and OECD guidelines for reproduction/developmental toxicity screening studies.

5.5 Body Weight Range:

A minimum of 20 grams at randomization.

5.6 Approximate Age:

42-63 days old at randomization.

5.7 Identification System:

Each mouse will be uniquely identified by tattoo markings applied to the tail. Individual cage cards will be affixed to each cage and will display the animal number, group number, study number, dosage level and sex of the animal.

5.8 Justification for Selection:

This species and strain of animal is recognized as appropriate for reproduction studies. WIL Research Laboratories, LLC has reproductive historical control data in the Crl:CD1(ICR) mouse. This animal model has been proven to be susceptible to the effects of reproductive toxicants.

6 SPECIFIC MAINTENANCE SCHEDULE:

6.1 Animal Housing:

The animals will be housed, 2-3 per cage, for at least 3 days following receipt. Thereafter, the mice will be housed individually. The F_0 males and females will be individually housed in solid bottom cages (plastic maternity cages) containing ground corncob nesting material (Bed-O' Cobs®) in an environmentally controlled room during the quarantine period and throughout the entire study until euthanasia. All F_1 offspring not euthanized at weaning will be housed by litter in the plastic cages with nesting material until postnatal day (PND) 28. F_1 offspring not selected for the maturation phase will be necropsied on PND 21. On PND 28, F_1 offspring will be individually housed in solid bottom cages (plastic maternity cages) containing ground corncob nesting material (Bed-O' Cobs®). The cages will be subject to routine cleaning at a frequency consistent with maintaining good animal health and WIL Standard Operating Procedures. The facilities at WIL Research Laboratories, LLC are fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

6.2 Environmental Conditions:

Controls will be set to maintain temperature at 71 ± 5°F (22 ± 3°C) and relative humidity at 50 ± 20%. Temperature and relative humidity will be monitored continuously. Data for these two parameters will be scheduled for automatic collection on an hourly basis. Fluorescent lighting controlled by light timers will provide illumination for a 12-hour light/dark photoperiod. The ventilation rate will be set at a minimum of 10 room air changes per hour, 100% fresh air.

6.3 Drinking Water:

Reverse osmosis-purified water will be available *ad libitum*. Filters servicing the automatic watering system are changed regularly according to WIL Standard Operating Procedures. The municipal water supplying the laboratory is analyzed according to WIL Standard Operating Procedures on a routine basis to ensure that contaminants are not present in concentrations that would be expected to affect the outcome of the study.

6.4 Basal Diet:

PMI Nutrition International, LLC Certified Rodent LabDiet® 5002 will be offered *ad libitum* during the study. Periodic analyses of the certified feed are performed by the manufacturer to ensure that heavy metals and pesticides are not present at concentrations that would be expected to affect the outcome of the study. Results of the analyses are provided to WIL Research Laboratories,

LLC by the manufacturer. Feeders will be changed and sanitized once per week.

6.5 Enrichment:

All animals will be offered Nestlets™ for enrichment that will be replaced as needed.

7 EXPERIMENTAL DESIGN:

7.1 Animal Receipt and Quarantine:

Each animal will be inspected by a qualified technician upon receipt. Mice judged to be in good health and suitable as test animals will be immediately placed in quarantine for a minimum of 9 days. All mice will be initially weighed, permanently identified by tattoo markings applied to the tail and receive a clinical observation. During the quarantine period, each mouse will be observed twice daily for changes in general appearance and behavior. Prior to the start of the in-life phase, those animals judged to be suitable test subjects will be identified and receive a detailed physical examination.

7.2 Randomization:

At the conclusion of the quarantine period, animals judged to be suitable test subjects and meeting acceptable body weight requirements, will be assigned at random using a computer program. At that time, the animal numbers and corresponding body weights will be entered into the WIL Toxicology Data Management System (WTDMS™). A printout containing the animal numbers and individual group assignments will be generated based on body weight stratification into a block design. Animals will then be arranged into the groups according to the printout. The control group and three test item groups will consist of 20 males and 20 females each.

Any animal assigned to the study that is found dead, euthanized *in extremis* or exhibits abnormal clinical signs, reduced food consumption or body weight losses prior to the start of dosing may be replaced by an animal of appropriate age when possible. Replacement animals will be arbitrarily assigned (not computer randomized) to the study based on comparable body weights (if possible) with respect to the animal that was replaced.

7.3 Route and Rationale of Test Item Administration:

The route of administration will be oral (gavage). Historically, this route has been used extensively for studies of this nature. Appropriately sized flexible,

Teflon®-shafted, stainless steel ball-tipped dosing cannulae will be used for the oral administration by gavage.

7.4 Organization of Test Groups, Dosage Levels and Treatment Regimen:

7.4.1 Organization of Test Groups:

The dose levels proposed for the current study are 0, 0.1, 0.5, and 5 mg/kg/day and are based on previous and ongoing general toxicity studies in mice. These levels are currently being tested in an ongoing (in-life dosing phase complete) subchronic toxicity 90-day gavage study (DuPont-18405-1307). The doses for the 90-day gavage study were based on results from a previous 28-day gavage study (DuPont-24459) in which doses of 0, 0.1, 3, and 30 mg/kg/day were tested.

The following table presents the study group arrangement.

Group Number	Test Item	Dosage Level (mg/kg/day)	Dosage Concentration (mg/mL)	Dosage Volume (mL/kg)	Number of Animals	
					Male	Female
1	Vehicle Control[b]	0	0	10	25	25
2	H-28548	0.1	0.01	10	25	25
3	H-28548	0.5	0.05	10	25	25
4	H-28548	5	0.5	10	25	25

[a] Dosage levels will be corrected for the purity of 84%.
[b] Deionized Water

7.4.2 Vehicle Control Item:

Deionized Water

7.4.3 F_0 Treatment Regimen:

The test and control items will be administered once daily at approximately the same time each day as follows:

7.4.3.1 Males:

F_0 males will be dosed for a minimum of 70 days prior to mating and continuing until the day prior to the scheduled euthanasia.

7.4.3.2 Females:

F_0 females will be dosed for a minimum of 14 days prior to mating and continuing throughout mating, gestation and lactation until Lactation Day (LD) 21 for females that deliver. For females

that do not have positive signs of mating or delivery, dosing will continue until one day prior to euthanasia.

7.4.3.3 F_1 Males and Females:

F_1 males and females will be dosed beginning in PND 21 until one day prior to euthanasia.

7.4.4 Adjustment of Dosages:

Individual dosages will be calculated based on the most recent body weight to provide the proper mg/kg/day dosage.

7.5 Preparation and Analysis of Test Item Formulations:

7.5.1 Method and Frequency of Preparation:

Based on the physical characteristics of the test substance, appropriate methods will be used to ensure the best possible formulations of the test substance in the vehicle. Dosing formulations will be stored refrigerated (2-8°C) for a maximum of 12 days. The Study Director or designee will visually inspect the formulations prior to the initiation of dosing. This visual inspection will be performed to ensure that the formulations are visibly homogeneous and acceptable for dosing. Any special procedures required for formulation will be documented according to Good Laboratory Practices and presented in the final report of this study. Test substance formulations will be prepared approximately weekly and divided into aliquots for daily dispensation. The test substance and vehicle formulations will be stirred continuously during dosing.

7.5.2 Homogeneity, Resuspension Homogeneity, Stability and Concentration Determination of Test Substance Formulations:

Stability and resuspension homogeneity were established on a previous study (Haas, Draft; WIL-189216). Test substance formulations were stable and 12 days of room temperature storage or refrigerated storage (2-8°C) at concentrations of 0.01 mg/mL and 100 mg/mL and homogenous following resuspension after 12 days of refrigerated storage (2-8°C). Stability and resuspension homogeneity will not be conducted on this study.

Homogeneity and concentration will be conducted on the first formulations prepared for dosing. Four 1-mL samples will be collected from the top, middle and bottom of the test substance formulations from the low and high dose groups and the samples analyzed to assess the

homogeneity of the test substance in the mixtures; the middle strata will serve as the measure of test substance concentration. Four 1-mL samples will be taken from the middle on the control and the mid-dose groups and analyzed for concentration of the test substance.

Concentration will be assessed on Week 4, 8, 12, 16 and 19 formulations prepared for dosing. Four 1-mL samples will be collected from the middle of each test substance formulation and the control group and analyzed for test substance content.

7.5.3 Sample Analysis:

Samples will be transferred to the Analytical Chemistry Department at WIL Research Laboratories, LLC for analysis. Analyses of test article formulations will be performed using a method developed and validated by WIL Research Laboratories, LLC. Initially, two of each set of four replicate, 1-mL samples will be analyzed; the remaining two 1-mL samples will be stored frozen (approximately -20°C) at WIL and will function as back-up samples. Back-up samples will be analyzed if requested by the Sponsor or Study Director or may be discarded following results that are within specifications and approval of the Study Director.

7.6 F_0 Breeding:

After a minimum of 70 days for males and 14 days of exposure for females, of exposure, one female will be cohabitated with one male mouse of the same treatment group, avoiding sibling mating, in a plastic cage for mating. Detection of mating will be confirmed by evidence of sperm in the vaginal lavage. After confirmation of mating, the female will be returned to an individual plastic cage and the day will be designated as day 0 of gestation.

A maximum of 14 days will be allowed for mating. After 14 days of mating, any females who have not shown evidence of breeding will be placed in a plastic cage containing nesting material.

7.7 F_0 Parturition and Lactation and F_1 Litters:

The day parturition is initiated will be designated as day 0 of lactation. Any difficulties at the time of parturition will be recorded. When parturition is judged to be complete, the sex of each pup will be determined, pups will be examined for gross malformations and the number of stillbirths and live pups will be recorded. Any changes or abnormalities in nesting and nursing behavior will be recorded. The dam and litter will remain together until postnatal day (PND) 21.

7.8 Identification of F_1 Litters:

Upon completion of delivery, all pups will be individually identified by tattoo markings applied to the digits. To reduce variability among the litters, on PND 4, eight pups of equal sex distribution (if possible) from each litter will be randomly selected. For litters consisting of fewer than eight pups, adjustments for litter sizes will not be performed. Following selection, the non-selected PND 4 pups will be euthanized by an intraperitoneal injection of sodium pentobarbital and discarded.

7.9 General Observations During the Experimental Period:

7.9.1 Parental Appearance and Behavior:

Each parental mouse (F_0) will be observed twice daily for moribundity and mortality, once in the morning and once in the afternoon. A detailed physical examination will be conducted weekly. Mortality and all signs of overt toxicity will be recorded on the day observed. The observations shall include, but are not limited to, evaluations for changes in appearance of the skin and fur, eyes and mucous membranes, respiratory, circulatory, autonomic and central nervous systems, somatomotor activity and behavior. During the period of expected parturition, the dams will be observed twice daily for dystocia, prolonged labor, delayed labor or other difficulties at parturition. All animals will also be observed on the day of necropsy and findings will be recorded.

During the treatment period, each animal will be observed at approximately 1-2 hours following each dose administration for findings that are potentially related to treatment of that might change before the next scheduled observation. Additional post dosing observation periods may be necessary and will be documented in the study records.

7.9.2 Parental Body Weights:

All animals will have a final body weight recorded on the day of euthanasia.

7.9.2.1 Males:

Recorded individually on a weekly basis, beginning on the first day of dose administration, until euthanasia.

7.9.2.2 Females:

Recorded individually on a weekly basis, beginning on the first day of dose administration, until evidence of copulation is observed and on gestation days 0, 4, 7, 11, 14, 17 and 20 and lactation days 1, 4, 7, 14 and 21.

For females with no evidence of mating, individual body weights will continue to be recorded on a weekly basis until euthanasia.

7.9.3 Parental Food Consumption*:

Individual food consumption will not be recorded during the breeding period because the animals are cohabitated at that time.

7.9.3.1 Males:

Recorded individually on a weekly basis, beginning on the first day of dose administration, until euthanasia.

7.9.3.2 Females:

Recorded individually on a weekly basis beginning on the first day of dose administration, until the start of the mating period. Individual food consumption will be recorded on the day evidence of copulation is observed (GD 0) and on gestation days 4, 7, 11, 14, 17 and 20 and lactation days 1, 4, 7, 14 and 21.

For females with no evidence of mating, individual food consumption will continue to be recorded on a weekly basis following the end of the mating period until euthanasia.

7.9.4 Examination of Offspring:

7.9.4.1 Appearance and Behavior:

All pups will be observed daily for general appearance and behavior and survival during lactation. A detailed physical examination will be recorded for each pup on PND 1, 4, 7, 14 and 21. Any abnormalities in nesting and nursing behavior will be recorded. The pups will be sexed on PND 0, 4, 14 and 21.

7.9.4.2 Body Weights:

Each pup will be weighed on PND 1, 4, 7, 14 and 21.

7.9.5 Pup Deaths:

7.9.5.1 Pups 0 to 4 Days of Age:

Moribund pups will be euthanized by an intraperitoneal injection of sodium pentobarbital. Stillborn pups, pups found dead between birth and PND 4, and any pups that are euthanized *in extremis* will be dissected (including the heart and the brain examined by a mid-coronal slice) by a technique described by Stuckhardt and Poppe (Stuckhardt and Poppe, 1984). If a skeletal anomaly is suspected, the pups will be eviscerated, cleared and stained with Alizarin Red S as described by Dawson (Dawson, 1926) and examined. Representative specimens with malformations may be preserved in 10% neutral buffered formalin at the discretion of the study director.

7.9.5.2 Pups 5 Days of Age to Weaning:

Moribund pups will be euthanized by an intraperitoneal injection of sodium pentobarbital (prior to PND 11) or by carbon dioxide inhalation. A gross necropsy will be performed on pups found dead or euthanized *in extremis*, and gross lesions will be saved for possible future histopathological examination in 10% neutral buffered formalin. If a skeletal anomaly is suspected, the pups will be eviscerated, cleared and stained with Alizarin Red S as described by Dawson (Dawson, 1926) and examined.

7.10 Selection of F_1 Generation and Termination of PND 21 Nonselected Pups:

One male and one female pup per litter will be selected for the F_1 generation on or prior to PND 21. Only pups not expected to survive due to notable physical limitations will not be available for selection. A detailed evaluation of each pup excluded from selection will be recorded.

All PND 21 pups not selected for the F_1 generation will be euthanized by carbon dioxide inhalation. A gross necropsy examination will be performed with an emphasis on evaluation of developmental morphology and organs of the reproductive system. Any gross lesions will be saved for possible future histopathological examination in 10% neutral buffered formalin.

7.11 Euthanasia of F_0 Generation:

7.11.1 Females:

7.11.1.1 Females Which Deliver:

On lactation day 21, all F_0 females that delivered will be euthanized by carbon dioxide inhalation. A gross examination will be performed and tissues preserved as described in Section 8.1. The number of former implantation sites will be recorded. Organ weights will be collected and tissues preserved as described in Section 8.2.

7.11.1.2 Females Which Fail to Deliver:

On post-mating day 25 (females with evidence of copulation) or post-cohabitation day 25 (females without evidence of copulation), the F_0 females which fail to deliver will be euthanized by carbon dioxide inhalation. A gross necropsy examination will be performed and tissues will be preserved as described in Section 8.1. Organ weights will be collected as described in Section 8.2 with the exception of any ammonium sulfide stained uterus, which will be discarded. Uteri which appear nongravid by macroscopic examination will be opened and placed in a 10% ammonium sulfide solution (Salewski, 1964) for detection of early implantation loss.

7.11.1.3 Females with Total Litter Loss:

Females with total litter loss will be euthanized by carbon dioxide inhalation on the same day. The number of former implantation sites will be recorded and the number of corpora lutea (if litter loss occurs on or before PND 4) will be recorded. A gross necropsy examination will be performed and tissues preserved as described in Section 8.1. Organ weights will be collected as described in Section 8.2.

7.11.1.4 F_0 Deaths and Animals Euthanized *in Extremis*:

Females not surviving until the scheduled euthanasia will have a gross necropsy examination performed and tissues preserved as described in Section 8.1. Animals not expected to survive to the next observation period (moribund) will be euthanized by carbon dioxide inhalation and have a gross necropsy examination performed and tissues preserved as described in Section 8.1.

Organ weights will not be collected from found dead or euthanized *in extremis* females. The number and location of implantation sites or scars will be recorded for females dying or euthanized during gestation and lactation. The number of corpora lutea will be recorded for females dying or euthanized during gestation and up to and including lactation day 4. Uteri which appear nongravid by macroscopic examination will be opened and placed in a 10% ammonium sulfide solution (Salewski, 1964) for detection of early implantation loss.

Viable fetuses will be euthanized by an intrathoracic injection of sodium pentobarbital. Recognizable fetuses will be examined externally for gross abnormalities. Representative specimens with malformations may be preserved in 10% neutral-buffered formalin, at the discretion of the study director. For females found dead or euthanized *in extremis* during lactation, all pups will be examined externally and subjected to a necropsy examination according to Section 7.9.5.

7.11.2 Males:

Following completion of the mating period, all F_0 males will be euthanized by carbon dioxide inhalation and subjected to a gross necropsy and tissue preservation as described in Section 8.1. Organ weights will be collected as described in Section 8.2.

Males not surviving until the scheduled euthanasia will be subjected to a gross necropsy and tissue preservation as described in Section 8.1. Any males not expected to survive to the next observation period (moribund) will be euthanized by carbon dioxide inhalation and also necropsied and have tissues preserved as described in Section 8.1. Organ weights will not be collected.

7.12 F_1 Generation General Observations During The Experimental Period:

7.12.1 F_1 Clinical Observations:

Following weaning and selection, the mice will be observed twice daily for moribundity and mortality, once in the morning and once in the afternoon. Clinical observations will be recorded daily. Mortality and all signs of overt toxicity will be recorded on the day observed. The observations shall include, but are not limited to, evaluation for changes in appearance of the skin and fur, eyes, mucous membranes, respiratory, circulatory, autonomic and central nervous system function,

somatomotor activity and behavior patterns. All animals will also be observed on the day of necropsy and any findings will be recorded.

During the treatment period, each animal will be observed at approximately 1-2 hours following each dose administration for findings that are potentially related to treatment of that might change before the next scheduled observation. Additional post dosing observation periods may be necessary and will be documented in the study records.

7.12.2 F_1 Body Weights and Food Consumption:

F_1 males and females will be have a body weight recorded approximately weekly, beginning with the start of test diet administration until euthanasia (PND 21, 28, 35 and 40). All animals will have a final body weight recorded on the day of euthanasia.

F_1 males and females will have food consumption recorded individually on an approximately weekly basis beginning on PND 28 until euthanasia (PND 28, 35 and 40). Food consumption will not be collected from PND 21 to PND 28 during group housing for the F_1 males and females.

7.13 F_1 Postweaning Developmental Landmarks:

Offspring selected for the F_1 generation will be evaluated for attainment of the following landmarks of sexual maturity:

7.13.1 Balanopreputial Separation:

Each male pup will be observed for balanopreputial separation beginning on PND 25 as described by Korenbrot *et al.* (Korenbrot 1977). Examination of the males will continue daily until balanopreputial separation is present. The body weight of each male will be recorded on the day of attainment of balanopreputial separation.

7.13.2 Vaginal Patency:

Each female pup will be observed for vaginal patency beginning on PND 21 (only those selected for the F_1 generation) as described by Adams *et al.* (Adams 1985). Examination of the females will continue daily until vaginal patency is present. The body weight of each female will be recorded on the day of attainment of vaginal patency.

7.14 Euthanasia of F_1 Generation:

7.14.1 Scheduled Necropsy

On PND 40, all F_1 animals will be euthanized by carbon dioxide inhalation. A gross necropsy examination will be performed with an emphasis on evaluation of developmental morphology and organs of the reproductive system. Any gross lesions will be saved for possible future histopathological examination in 10% neutral buffered formalin.

7.14.2 Unscheduled Deaths or Animals Euthanized *in Extremis*

Any F_1 animals not surviving until the scheduled euthanasia or not expected to survive to the next observation period (euthanized by carbon dioxide inhalation) will be necropsied. A gross necropsy examination will be performed with an emphasis on evaluation of developmental morphology and organs of the reproductive system. Any gross lesions will be saved for possible future histopathological examination in 10% neutral buffered formalin.

8 ANATOMIC PATHOLOGY:

8.1 Macroscopic Examination:

A complete necropsy will be conducted on all F_0 parental animals dying spontaneously, euthanized *in extremis* (by carbon dioxide inhalation) or at termination. This will include examination of the external surface, all orifices, the cranial cavity, the external surface of the brain and the thoracic, abdominal and pelvic cavities including viscera. For F_0 females, the number of former implantation sites will be recorded.

At the time of necropsy, the following tissues and organs will be collected and placed in 10% neutral-buffered formalin (except as noted):

Coagulating gland	Prostate
Kidneys (2)	Seminal vesicles (2)
Liver	Testes with epididymides (2)[a]
Mammary gland (females only)	and vas deferens
Ovaries and oviduct (2)	Uterus[b] with cervix and vagina
Pituitary	All gross lesions[c]

a - Testes and epididymides will be fixed in Bouin's solution.
b - Any uterus stained in 10% ammonium solution for detection of implantation sites will be discarded and will not be preserved in 10% neutral buffered formalin.
c - Representative sections of corresponding organs from a sufficient number of controls will be retained for comparison, if possible.

8.2 Organ Weights:

The following organs will be weighed from all F_0 parental animals euthanized at scheduled termination. Organ-to-final-body weight and organ-to-brain weight ratios will be evaluated.

Brain	Ovaries (with oviducts)
Epididymides*	Pituitary
Kidneys	Testes*
Liver	

* - These paired organs will be weighed separately.

8.3 Microscopic Examination:

Microscopic examination of hematoxylin-eosin stained paraffin sections will be performed on the following tissues from all F_0 parental animals from the control and high-dose groups and from all parental animals dying spontaneously or euthanized *in extremis*. If a target organ is identified in the high-dose group, this organ will be examined from all animals in the low and mid-dose groups (at additional cost):

Cervix	Seminal vesicles
Coagulating gland	Testes
Epididymides	Uterus
Ovaries and oviduct	Vagina
Prostate	All gross (internal) lesions

The slides will be prepared by WIL Research Laboratories, LLC and then shipped to Sponsor at the address and contact below for examination by the Principal Investigator, Pathology.

Carolyn Lloyd
DuPont Haskell Global Centers for Health & Environmental Sciences
Investigative Sciences, S320/531
1090 Elkton Road
Newark, DE 19714-0050
Tel: 302-366-5401
Fax: 302-451-4530
Email: carolyn.w.lloyd@usa.dupont.com

The examination of the slides will be performed by the Principal Investigator for Pathology. A final pathology report will be prepared and submitted to WIL Research for inclusion as an appendix in the main study final report. A Quality Assurance and GLP compliance statement signed by the performing laboratory

will be provided to the WIL Study Director for inclusion in the Final Report. The Sponsor is responsible for archiving of raw data associated with the conduct of the pathological examination.

9 DURATION OF STUDY:

The two generations to be studied (parental animals and first generation offspring) will be termed F_0 and F_1, respectively. The conduct of this study will require approximately 22 weeks for acclimation, mating, gestation and lactation of the F_0 generation.

10 STATISTICAL METHODS:

All analyses will be two-tailed for significance levels of 5% and 1%. All means will be presented with standard deviations. All statistical tests will be performed by a computer with appropriate programming as referenced below. The litter, rather than the pup, will be considered as the experimental unit.

10.1 Parental In-Life Data:

Continuous data variables [mean body weights, body weight gains and food consumption at each interval], pre-coital intervals, gestation length, former implantation sites, unaccounted-for sites, mean days of attainment of developmental landmarks (balanopreputial separation and vaginal patency) and the body weight on the day of attainment will be subjected to a parametric one-way analysis of variance (ANOVA) (Snedecor, 1980) to determine intergroup difference. If the results of the ANOVA are significant ($p<0.05$), Dunnett's test (Dunnett, 1964) will be applied to the data to compare the treated groups to the control group.

Male and female mating, fertility, copulation and conception indices of the treated groups will be compared to the control group using the Chi-square test with Yates' correction factor (Hollander, 1999).

10.2 Litter Data:

The mean litter proportions (% per litter) of pup viability during the postnatal period and sex ratio at birth will be subjected to the Kruskal-Wallis nonparametric ANOVA test (Kruskal, 1952) to determine intergroup difference. If the results of the ANOVA are significant ($p<0.05$), the Dunn's Test (Dunn, 1964) will be applied to compare the treated groups to the control group. Mean numbers of pups born, live litter size and litter weights will be subjected to the parametric ANOVA test (Snedecor, 1980) and Dunnett's test (Dunnett, 1964) as described above with the litter representing the experimental unit.

10.3 Histopathology and Organ Weight Data:

Histopathological findings of each treated group will be compared to those of the control group by the Fisher's Exact test (Steel, 1980). Organ weights (absolute and relative to body weights and relative to brain weights) will be subjected to a parametric ANOVA test (Snedecor, 1980) and Dunnett's test (1964) as described above.

11 QUALITY ASSURANCE:

The study will be audited by the WIL Quality Assurance Unit while in progress to assure compliance with the study protocol and protocol amendments, WIL Standard Operating Procedures and the appropriate provisions of EPA/TSCA and FIFRA Good Laboratory Practice Standards published in the Federal Register (40 CFR Part 792 and 40 CFR Part 160) and the OECD Principles of Good Laboratory Practice. The final report will be audited by the WIL Quality Assurance Unit prior to submission to the Sponsor Representative to assure that the final report accurately describes the conduct and the findings of the study.

The pathological examination of the slides will be conducted following the Standard Operating Procedures of the performing laboratory and in accordance with GLPs. Quality Assurance monitoring of these analyses for SOP and GLP compliance is the responsibility of the performing laboratory. Inspection reports will be supplied to the Study Director. Upon completion of the prescribed activities and submission of the results to the Sponsor and Study Director the performing laboratory will provide a signed Quality Assurance Statement to the Sponsor (copy to the Study Director). The results will be included in the final report.

This study will be included on the WIL master list of regulated studies.

12 RECORDS TO BE MAINTAINED:

All original raw data records, as defined by WIL SOPs and the applicable GLPs, will be stored as described in Section 13 in the Archives at WIL Research Laboratories, LLC.

The Sponsor will be responsible for the archival of the raw data and records for the pathological examination.

13 WORK PRODUCT:

The Sponsor will have title to all documentation records, raw data, slides, specimens and other work product generated during the performance of the study. Any remaining formulation samples will be discarded after the issuance of the Final Report. All work product, including raw paper data, pertinent electronic storage

media and specimens, will be retained for a period of six months following issuance of the final report in the Archives at WIL Research Laboratories, LLC. Thereafter, WIL Research Laboratories, LLC will charge a monthly archiving fee for retention of all work product. All work product will be stored in compliance with regulatory requirements.

Any work product, including documents, specimens, and samples, that are required by this protocol, its amendments, or other written instructions of the Sponsor, to be shipped by WIL Research Laboratories, LLC to another location will be appropriately packaged and labeled as defined by WIL's SOPs and delivered to a common carrier for shipment. WIL Research Laboratories, LLC will not be responsible for shipment following delivery to the common carrier.

All work product generated at a performing laboratory will be retained at an appropriate archive facility as designated by the SOPs of the performing laboratory.

14 REPORTS:

The final report will contain a summary, test item data, methods and procedures, maternal and pup data WIL Historical Control Data, the analytical chemistry report, pathology report and an interpretation and discussion of the study results. The final report will be comprehensive and shall define level(s) inducing toxic effects as well as no-effect level(s) under the conditions of this investigation. The report will contain all information necessary to conform with current OPPTS and OECD specifications.

WIL Research Laboratories, LLC will submit one copy of an audited draft report in a timely manner upon completion of data collection prior to issuance of the final report. One revision will be permitted as part of the cost of the study, from which the Sponsor's reasonable revisions and suggestions will be incorporated into the final report, as appropriate. Additional changes or revisions may be made, at extra cost. It is expected that the Sponsor will review the draft report and provide comments to WIL Research Laboratories, LLC within a two-month time frame following submission. WIL Research Laboratories, LLC will submit the final report within one month following receipt of comments. If the Sponsor's comments and/or authorization to finalize the report have not been received at WIL Research Laboratories, LLC within one year following submission of the draft report, WIL Research Laboratories, LLC may elect to finalize the report following appropriate written notification to the Sponsor. Two electronic copies (PDF) of the final report on CD-R will be provided. Requests for paper copies of the final report may result in additional charges.

15 ANIMAL WELFARE ACT COMPLIANCE:

This study will comply with all applicable sections of the Final Rules of the Animal Welfare Act (AWA) regulations (9 CFR Parts 1, 2 and 3). The Sponsor should make particular note of the following:

- The Sponsor Representative's signature on this protocol documents for the Study Director the Sponsor's assurance that the study described in this protocol does not unnecessarily duplicate previous experiments.
- Whenever possible, procedures used in this study have been designed to avoid or minimize discomfort, distress or pain to animals. All methods are described in this study protocol or in written laboratory Standard Operating Procedures.
- Animals that experience severe pain or distress that cannot be relieved will be painlessly euthanized as deemed appropriate by the veterinary staff and Study Director. The Sponsor will be advised by the Study Director of all circumstances which could lead to this action in as timely a manner as possible.
- Methods of euthanasia used during this study are in conformance with the above-referenced regulation.
- The Sponsor/Study Director has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and has provided a written narrative description (AWA covered species) of the methods and sources used to determine that alternatives are not available.

16 PROTOCOL MODIFICATION:

Modification of the protocol may be accomplished during the course of this investigation. However, no changes will be made in the study design without the verbal or written permission of the Sponsor. In the event that the Sponsor verbally requests or approves a change in the protocol, such changes will be made by appropriate documentation in the form of protocol amendment. All alterations of the protocol and reasons for the modification(s) will be signed by the Study Director and the Sponsor Representative.

17 REFERENCES:

Adams, J.; Buelke-Sam, J.; Kimmel, C.A.; Nelson, C.J.; Reiter, L.W.; Sobotka, T.J.; Tilson, H.A.; Nelson, B.K. Collaborative behavioral teratology study: protocol design and testing procedure. *Neurobehavioral Toxicology and Teratology* **1985**, *7*, 579-586.

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Hollander, M.; Wolfe, D.A. *Nonparametric Statistical Methods*, 2nd ed.; Hollander, M., Wolfe, D.A., Eds.; John Wiley and Sons, Inc.: New York, NY, 1999; p 468.

Korenbrot, C.C.; Huhtaniemi, I.T.; Weiner, R.W. Preputial separation as an external sign of pubertal development in the male rat. *Biology of Reproduction* 1977, *17*, 298-303.

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Salewski, E. Färbemethode zum makroskopischen Nachweis von Implantationsstellen am Uterus der Ratte. [Staining method for a macroscopic test for implantation sites in the uterus of the rat]. *Naunyn - Schmiedebergs Archiv für Experimentelle Pathologie und Pharmakologie* 1964, *247*, 367.

Snedecor, G.W.; Cochran, W.G. One Way Classifications; Analysis of Variance. In *Statistical Methods*, 7th ed.; The Iowa State University Press: Ames, IA, 1980; pp 215-237.

Steel, R.G.D.; Torrie, J.H. *Principles and Procedures of Statistics, A Biometrical Approach*, 2nd ed.; McGraw-Hill Book Company: New York, NY, 1980; pp 504-506.

Stuckhardt, J.L.; Poppe, S.M. Fresh visceral examination of rat and rabbit fetuses used in teratogenicity testing. *Teratogenesis, Carcinogenesis and Mutagenesis* **1984,** *4,* 181-188.

18 PROTOCOL APPROVAL:

Sponsor approval received via email on 4 Jan 2010.
Date

E. I. du Pont de Nemours and Company

Susan M. Munley
Susan M. Munley, MA
Sponsor Representative

8 Jan 2010
Date

WIL Research Laboratories, LLC

Tammye L. Edwards
Tammye L. Edwards, BS, LAT
Study Director

4 Jan 2010
Date

Donald G. Stump
Donald G. Stump, PhD, DABT
Director, Developmental and
Reproductive Toxicology

4 Jan 2010
Date

Study Number: WIL-189225

PROTOCOL AMENDMENT 1

Sponsor: E.I. du Pont de Nemours and Company

Title of Study:

An Oral (Gavage) Reproduction/Developmental Toxicity Screening Study of H-28548 in Mice

Protocol Modifications:

1) Applicable Protocol Sections: 3

   The proposed audited draft date is 10 September 2010.

2) Applicable Protocol Sections: 7.2

   The control group and three test item groups will consist of 25 males and 25 females each.

3) Applicable Protocol Sections: 7.3

   Appropriately sized flexible, Teflon®-shafted, stainless steel dosing cannulae will be used for the oral administration by gavage. The dosing cannulae may or may not be ball-tipped as appropriate for the age of the animal.

4) Applicable Protocol Sections: 7.4.3.2

   F_0 females will be dosed for a minimum of 14 days prior to mating and continuing throughout mating, gestation and lactation until Lactation Day (LD) 20, inclusively, for females that deliver.

5) Applicable Protocol Sections: 7.6

   Detection of mating will be confirmed by the appearance of a vaginal copulatory plug.

6) Applicable Protocol Sections: 7.9.2.2

For those females with evidence of mating, body weights will be recorded individually on a weekly basis, beginning on the first day of dose administration, until evidence of copulation is observed and on gestation days 0, 4, 7, 11, 14 and 18 and on lactation days 1, 4, 7, 14 and 21.

7) Applicable Protocol Sections: 7.11.1.2

On post-mating day 23 (females with evidence of mating) or post-cohabitation day 23 (females without evidence of copulation), the F_0 females which fail to deliver will be euthanized by carbon dioxide inhalation.

8) Applicable Protocol Sections: 7.12.1

The second sentence of the first paragraph is changed to the following:
A detailed physical examination will be conducted weekly.

9) Applicable Protocol Sections: 7.12.2

F_1 males and females will be have a body weight recorded approximately weekly, beginning with the start of test substance administration until euthanasia (PND 21, 28, 35 and 40).

10) Applicable Protocol Sections: 8.1

Footnote "a" should read:

Testes and epididymides will be fixed in Bouin's solution. Care will be taken to ensure separation between the left and right organs.

11) Applicable Protocol Sections: 8.3

Microscopic examination of hematoxylin-eosin stained paraffin sections will be performed on the listed tissues from all F_0 parental animals from the control and high-dose groups and from all parental animals dying spontaneously or euthanized *in extremis* and from any animals in the low and mid dose groups with impaired fertility (males that did not sire a litter or females that did not deliver a litter).

Reasons for Protocol Modification:

1) Audited report date added to protocol.

2) The number of animals in each dose group was increased to 25 per sex to ensure an adequate number of pregnant females per group.

3) Ball-tipped steel gavage needles are not used on pups under 28 days of age.

4) Clarification of dosing regimen for the females that deliver.

5) Vaginal lavages are not used for the determination of pregnancy in mice, just the presence of copulatory plugs.

6) Correction of gestation days body weights are collected and mice deliver on GD 18.

7) Change in the post-mating or post-cohabitation day that the mice will be euthanized on due to the mouse having a shorter gestation length.

8) F_1 clinical observations were changed to weekly physical examinations for consistency with the F_0 observations.

9) Correction of typographical error.

10) Clarification of maintenance of left and right organ separately for necropsy tissue collection.

11) Addition of microscopic evaluation of animals in the low and mid dose group that have impaired fertility.

Approval:

Sponsor's approval was obtained via email on January 19, 2010.

Tammye L. Edwards, BS, LAT
Study Director

22 Jan 2010
Date

Donald G. Stump, PhD, DABT
Director, Developmental and
Reproductive Toxicology

22 Jan 2010
Date

Susan M. Munley, MA
Sponsor Representative

29 Jan 2010
Date

Study Number: WIL-189225

PROTOCOL AMENDMENT 2

Sponsor: E.I. du Pont de Nemours and Company

Title of Study:

An Oral (Gavage) Reproduction/Developmental Toxicity Screening Study of H-28548 in Mice

Protocol Modifications:

1) **5.6 Approximate Age:**

   The approximate age of the males at randomization will be 42-63 days. The approximate age of the females at randomization will be 70-80 days.

2) **6.1 Animal Housing:**

   The females will be housed individually in solid bottom cages upon arrival.

Reasons for Protocol Modification:

1) Age of mice changed to ensure sexual maturity at the time of breeding.

2) The caging upon arrival was changed to individual due to the increase in age of the animal upon arrival.

Approval:

Sponsor's approval was obtained via email on February 10, 2010.

WIL Research Laboratories, LLC

Tammye L. Edwards, BS, LAT
Study Director

12 Feb 2010
Date

Donald G. Stump, PhD, DABT
Director, Developmental and
Reproductive Toxicology

12 Feb 2010
Date

E.I. du Pont de Nemours and Company

Susan M. Munley, MA
Sponsor Representative

15 Feb 2010
Date

Study Number: WIL-189225

PROTOCOL AMENDMENT 3

Sponsor: E.I. du Pont de Nemours and Company

Title of Study:

An Oral (Gavage) Reproduction/Developmental Toxicity Screening Study of H-28548 in Mice

Protocol Modifications:

1) **7.9.3.2 Females:**

The first paragraph is changed to the following:

Recorded individually on a weekly basis beginning on the first day of dose administration, until the start of the mating period. Individual food consumption will be recorded on the day evidence of copulation is observed (GD 0) and on gestation days 4, 7, 11, 14 and 18 and lactation days 1, 4, 7, 14 and 21.

Reasons for Protocol Modification:

1) Gestation food consumption intervals corrected for the mouse gestational period.

Approval:

Sponsor's approval was obtained via email on March 11, 2010.

WIL Research Laboratories, LLC

Tammye L. Edwards, BS, LAT
Study Director

11 March 2010
Date

Donald G. Stump, PhD, DABT
Director, Developmental and
Reproductive Toxicology

16 Mar 2010
Date

E.I. du Pont de Nemours and Company

Susan M. Munley, MA
Sponsor Representative

12 March 2010
Date

Study Number: WIL-189225

PROTOCOL AMENDMENT 4

Sponsor: E.I. du Pont de Nemours and Company

Title of Study:

An Oral (Gavage) Reproduction/Developmental Toxicity Screening Study of H-28548 in Mice

Protocol Modifications:

1) **1 Objective:**

   The following is added to this section:

   In addition, a toxicokinetic assessment of plasma levels of the test article will be performed in the F_0 females and the F_1 pups at culling and on PND 21 and PND 40.

2) **2.4 WIL Departmental Responsibilities:**

   The following person is added to this section:

   Carol S. Wally, BA, SRS, RLATG
   Group Supervisor, Sample Processing Laboratory

3) The following sections are added to the protocol:

   2.5 Principal Investigator, Plasma Sample Analysis and Report:

   Michael Mawn, PhD
   Senior Research Chemist
   DuPont Stine-Haskell Research Center
   1090 Elkton Road
   Bldg. S-315 Lab 1333
   Newark, DE 19714-0030
   Tel: 302-451-3365
   Email: michael.p.mawn@usa.dupont.com

4) The following sections are added to the protocol:

7.15 Plasma Sample Collection and Analysis:

7.15.1 Interval:

Blood samples will be collected at the time of scheduled necropsy on LD 21 from 5 randomly selected F_0 females per group that delivered. A blood sample will be collected from all females that failed to deliver on post-mating day 23 at the time of the scheduled necropsy.

In addition, all control females that delivered but were not selected for blood collection as indicated above, will have blood samples taken on LD 21 at the time of scheduled necropsy to provide control animal plasma for method development work to be conducted by the Sponsor. These control samples will be processed and shipped as described for the study samples.

Blood samples will also be collected from the F_1 culled pups on PND 4 from 10 randomly chosen litters in each group following culling and data collection.

On PND 21, blood samples will be collected from 5 randomly selected F_1 males and females in each group at the time of the scheduled necropsy that are not selected for the F_1 generation.

On PND 40, blood samples will be collected from 5 randomly selected F_1 males and females in each group at the time of the scheduled necropsy.

7.15.2 Route of Collection:

Blood samples will be collected via the vena cava following euthanasia by carbon dioxide inhalation from the F_0 females and the F_1 PND 21 and PND 40 animals.

Blood samples will be collected via decapitation from the PND 4 pups and pooled by litter.

7.15.3 Target Blood Volume:

For the F_0 females and the F_1 PND 21 and PND 40 animals, 1.0 mL or as much as possible, will be collected into pre-chilled, uniquely-labeled tubes. For the PND 4 pups, blood will be pooled by litter from all the culled pups in each litter to obtain as much blood as possible.

7.15.4 Anticoagulant:

K_3EDTA

7.15.5 Sample Handling and Plasma Preparation:

Samples will be kept on wet ice, protected from light, until centrifugation. All samples will be centrifuged [approximately 3000 rpm (approximately 2060 x g) for approximately 10 min] at approximately 4°C. Plasma will be transferred into new, uniquely-labeled polypropylene tubes.

7.15.6 Label Information:

Samples will include study number, dose group, animal number, interval, sample type and date and time of blood collection.

7.15.7 Storage:

Plasma samples will be stored frozen at approximately -20°C until analysis. The time and date the samples were placed in the freezer will be recorded.

7.15.8 Sample Shipment:

Frozen samples in dry ice, an inventory list and documentation of actual blood collection times for each animal will be shipped on the first Monday or Tuesday after the last sample is collected. The recipient will be notified at least 24 hours in advance of any shipment. Samples will be shipped overnight to:

Michael Mawn, PhD
Senior Research Chemist
DuPont Stine-Haskell Research Center
1090 Elkton Road
Bldg. S-315 Lab 1334
Newark, DE 19714-0030
Tel: 302-451-3365
Email: michael.p.mawn@usa.dupont.com

7.15.9 Plasma Analyses and Report:

Plasma samples will be analyzed for the test article content after solvent protein precipitation with LC/MS/MS analysis. The method of analysis will be documented in the study records and final report. The Principal Investigator for the plasma analysis will be responsible for all bioanalytical delegated-phase activities and will issue a formal bioanalytical/plasma analyses report from the data generated that will be included as an appendix in the final report. A Quality Assurance and GLP compliance statement signed by Sponsor and archival location of the data will be provided to the WIL Study Director for inclusion in the Final Report.

5) **11 Quality Assurance:**

The first sentence of the second paragraph is changed to the following:

The plasma samples analysis and the pathological examination of the slides will be conducted following the Standard Operating Procedures of the performing laboratory and in accordance with GLPs.

6) **12 Records To Be Maintained:**

The second paragraph is changed to the following:

The Sponsor will be responsible for the archival of the raw data and records for the plasma sample analyses and the pathological examination.

7) **13 Work Product:**

The second sentence of the first paragraph is changed to the following:

Any remaining plasma samples and formulation samples will be discarded after the issuance of the Final Report.

8) **14 Reports:**

The second sentence of the first paragraph is changed to the following:

The final report will contain a summary, test item data, methods and procedures, maternal and pup data WIL Historical Control Data, the analytical chemistry report, the plasma analysis report, the pathology report and an interpretation and discussion of the study results.

Reasons for Protocol Modification:

1-8) Blood collection for plasma sample analyses is added to the protocol at the Sponsor's request to characterize the exposure levels of the test substance.

Approval:

Sponsor's approval was obtained via email on April 14, 2010.

WIL Research Laboratories, LLC

Tammye L. Edwards, BS, LAT
Study Director

15 April 2010
Date

Donald G. Stump, PhD, DABT
Director, Developmental and
Reproductive Toxicology

15 Apr 2010
Date

E. I. du Pont de Nemours and Company

Susan M. Munley, MA
Sponsor Representative

19 Apr 2010
Date

Study Number: WIL-189225

PROTOCOL AMENDMENT 5

Sponsor: E.I. du Pont de Nemours and Company

Title of Study:

An Oral (Gavage) Reproduction/Developmental Toxicity Screening Study of H-28548 in Mice

Protocol Modifications:

1) **7.4.3.2 Females:**

The first sentence of this section is changed to the following:

F_0 females will be dosed for a minimum of 14 days prior to mating and continuing throughout mating, gestation and lactation until Lactation Day (LD) 20, inclusively, for females that deliver, with the exception of the 5 females/group that are selected for blood collection on LD 21, which will also receive a dose on LD 21.

2) **7.4.3.3 F_1 Males and Females:**

F_1 males and females will be dosed beginning in PND 21 through PND 40, inclusively.

3) **7.15.1 Interval:**

This section is changed to the following:

Blood samples will be collected at 2 hours post dose administration on LD 21 at necropsy from 5 randomly selected F_0 females per group that delivered. A blood sample will be collected from all females that failed to deliver on post-mating day 23 at the time of the scheduled necropsy (not timed).

In addition, all control females that delivered but were not selected for blood collection as indicated above, will have blood samples taken on LD 21 at the time of scheduled necropsy (not timed) to provide control animal plasma for method

development work to be conducted by the Sponsor. These control samples will be processed and shipped as described for the study samples.

Blood samples will also be collected from the F_1 culled pups on PND 4 from 10 randomly chosen litters in each group following culling and data collection.

On PND 21, blood samples will be collected from 5 randomly selected F_1 males and females in each group at the time of the scheduled necropsy (not timed) that are not selected for the F_1 generation.

On PND 40, blood samples will be collected at 2 hours dose administration at necropsy from 5 randomly selected F_1 males and females in each group.

Reasons for Protocol Modification:

1-3)Per the Sponsor, the most appropriate time of blood collection is 2 hours following dose administration; therefore, an additional dose day for the LD 21 females selected for blood collection and an additional dose day for all F_1 pups on PND 40 was added and the time and days of sample collection was added as appropriate.

Approval:

Sponsor's approval was obtained via email on May 3, 2010.

WIL Research Laboratories, LLC

Tammy L. Edwards — 4 May 2010
Tammy L. Edwards, BS, LAT — Date
Study Director

Donald G. Stump — 4 May 2010
Donald G. Stump, PhD, DABT — Date
Director, Developmental
and Reproductive Toxicology

E. I. du Pont de Nemours and Company

Susan M. Munley — 5 May 2010
Susan M. Munley, MA — Date
Sponsor Representative

PROTOCOL

AN ORAL (GAVAGE) REPRODUCTION/DEVELOPMENTAL TOXICITY SCREENING STUDY OF H-28548 IN MICE

(U.S. EPA OPPTS 870.3550 and OECD Guideline 421)

Submitted To:

E.I. du Pont de Nemours and Company
Wilmington, Delaware 19898

DuPont Work Request Number: 18405
DuPont Service Code: 1037
DuPont Study Number: 18405-1037

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-8946

1 OBJECTIVE:

To provide preliminary information on the potential adverse effects of the test substance on male and female reproduction within the scope of a screening study. This will encompass gonadal function, mating behavior, conception, parturition and lactation of the F_0 generation and the development of offspring from conception through day 40 of postnatal life.

In addition, a toxicokinetic assessment of plasma levels of the test article will be performed in the F_0 females and the F_1 pups at culling and on PND 21 and PND 40.

This study is subject to the applicable regulations of the Organisation for Economic Cooperation and Development (OECD) Guideline for Testing of Chemicals, Guideline 421, Reproduction/Development Toxicity Screening Test, July 27, 1995, and the United States Environmental Protection Agency (EPA) Health Effects Test Guidelines OPPTS 870.3550, Reproduction/Developmental Toxicity Screening Test, July 2000 and will be conducted in accordance with the EPA/TSCA and FIFRA (40 CFR Part 792 and 40 CFR Part 160) and the OECD Principles of Good Laboratory Practice.

2 PERSONNEL INVOLVED IN THE STUDY:

2.1 Study Representative:

Susan M. Munley, MA
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2.3 WIL Study Director:

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2.4 WIL Departmental Responsibilities:

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Assistant Director, Neurosciences

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Walter R. Miller, BS, DVM
Clinical Veterinarian,
Head of Surgery and Experimental Medicine

Ronald E. Wilson, BS
Director, Informational Systems

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Bennett J. Varsho, MPH, DABT
Operations Manager, Developmental and
Reproductive Toxicology and the Formulations Laboratory

Carol S. Wally, BA, SRS, RLATG
Group Supervisor, Sample Processing Laboratory

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Robert A. Wally, BS, RAC
Manager, Reporting and Regulatory
Technical Services

2.5 Principal Investigator, Plasma Sample Analysis and Report:

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3 STUDY SCHEDULE:

Proposed Experimental Starting (Animal Receipt) Date:	5 January 2010
Proposed Experimental Start (First Day of Dosing) Date:	14 January 2010
Proposed Experimental Completion/Termination Date:	4 June 2010
Proposed Audited Report Date:	~~To be determined~~10 September 2010

4 TEST SUBSTANCE DATA:

4.1 Test Substance Shipment:

Test substance and applicable documentation, including a Certificate of Analysis, will be shipped under Sponsor's responsibility to:

Formulations Laboratory (WIL-189225; Tammye Edwards)
Attn: Larry Blessing
WIL Research Laboratories, LLC
1407 George Road
Ashland, Ohio 44805-8946

4.2 Identification:

H-28548 or HFPO Dimer Acid Ammonium Salt

4.3 Haskell Test Substance Number:

H-28548

4.4 Lot Number:

E109540-44A

4.5 Expiration/Retest Date:

13 June 2011

4.6 Purity:

84%

4.7 Storage Conditions:

Controlled room temperature and humidity (approximately 18° to 24°C and 20% to 70% relative humidity)

4.8 Stability:

The analysis was performed by the Sponsor and documented on the Certificate of Analysis.

4.9 Physical Description:

To be documented by WIL Research Laboratories, LLC.

4.10 Reserve Samples:

Reserve samples of the test substance will be taken in accordance with WIL Standard Operating Procedures and stored in the Archives at WIL Research Laboratories, LLC indefinitely, unless otherwise specified.

4.11 Personnel Safety Data:

See the Material Safety Data Sheet (MSDS) provided by the Sponsor.

4.12 Test Substance Disposition:

With the exception of the reserve sample for each batch of test substance, which will be archived as described, all neat test substance remaining at completion of the in-life phase of the study will be kept for subsequent studies.

5 TEST SYSTEM:

5.1 Species:

Mouse

5.2 Strain:

Charles River Crl:CD1(ICR)

5.3 Source:

Males: Charles River Laboratories, Inc., Raleigh, NC
Females: Charles River Laboratories, Inc., Kingston, NY

5.4 Number on Study:

100 males and 100 females (minimum of 120 males and 120 females purchased; males and females will be ordered from separate facilities to ensure the avoidance of sibling mating). Animals not assigned to study will be transferred to the stock animal colony or will be euthanized by carbon dioxide inhalation and the carcasses discarded.

The number of animals used on this study is consistent with OPPTS and OECD guidelines for reproduction/developmental toxicity screening studies.

5.5 Body Weight Range:

A minimum of 20 grams at randomization.

5.6 Approximate Age:

The approximate age of the males at randomization will be 42-63 days. The approximate age of the females at randomization will be 70-80 days.~~42-63 days old at randomization.~~

5.7 Identification System:

Each mouse will be uniquely identified by tattoo markings applied to the tail. Individual cage cards will be affixed to each cage and will display the animal number, group number, study number, dosage level and sex of the animal.

5.8 Justification for Selection:

This species and strain of animal is recognized as appropriate for reproduction studies. WIL Research Laboratories, LLC has reproductive historical control data in the Crl:CD1(ICR) mouse. This animal model has been proven to be susceptible to the effects of reproductive toxicants.

6 SPECIFIC MAINTENANCE SCHEDULE:

6.1 Animal Housing:

The animals will be housed, 2-3 per cage, for at least 3 days following receipt. Thereafter, the mice will be housed individually. The females will be housed individually in solid bottom cages upon arrival.The F_0 males and females will be individually housed in solid bottom cages (plastic maternity cages) containing ground corncob nesting material (Bed-O' Cobs®) in an environmentally controlled room during the quarantine period and throughout the entire study until euthanasia. All F_1 offspring not euthanized at weaning will be housed by litter in the plastic cages with nesting material until postnatal day (PND) 28. F_1 offspring not selected for the maturation phase will be necropsied on PND 21. On PND 28, F_1 offspring will be individually housed in solid bottom cages (plastic maternity cages) containing ground corncob nesting material (Bed-O' Cobs®). The cages will be subject to routine cleaning at a frequency consistent with maintaining good animal health and WIL Standard Operating Procedures. The facilities at WIL Research Laboratories, LLC are fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

6.2 Environmental Conditions:

Controls will be set to maintain temperature at 71 ± 5°F (22 3°C) and relative humidity at 50 ± 20%. Temperature and relative humidity will be monitored continuously. Data for these two parameters will be scheduled for automatic

collection on an hourly basis. Fluorescent lighting controlled by light timers will provide illumination for a 12-hour light/dark photoperiod. The ventilation rate will be set at a minimum of 10 room air changes per hour, 100% fresh air.

6.3 Drinking Water:

Reverse osmosis-purified water will be available *ad libitum*. Filters servicing the automatic watering system are changed regularly according to WIL Standard Operating Procedures. The municipal water supplying the laboratory is analyzed according to WIL Standard Operating Procedures on a routine basis to ensure that contaminants are not present in concentrations that would be expected to affect the outcome of the study.

6.4 Basal Diet:

PMI Nutrition International, LLC Certified Rodent LabDiet® 5002 will be offered *ad libitum* during the study. Periodic analyses of the certified feed are performed by the manufacturer to ensure that heavy metals and pesticides are not present at concentrations that would be expected to affect the outcome of the study. Results of the analyses are provided to WIL Research Laboratories, LLC by the manufacturer. Feeders will be changed and sanitized once per week.

6.5 Enrichment:

All animals will be offered Nestlets™ for enrichment that will be replaced as needed.

7 EXPERIMENTAL DESIGN:

7.1 Animal Receipt and Quarantine:

Each animal will be inspected by a qualified technician upon receipt. Mice judged to be in good health and suitable as test animals will be immediately placed in quarantine for a minimum of 9 days. All mice will be initially weighed, permanently identified by tattoo markings applied to the tail and receive a clinical observation. During the quarantine period, each mouse will be observed twice daily for changes in general appearance and behavior. Prior to the start of the in-life phase, those animals judged to be suitable test subjects will be identified and receive a detailed physical examination.

7.2 Randomization:

At the conclusion of the quarantine period, animals judged to be suitable test subjects and meeting acceptable body weight requirements, will be assigned at

random using a computer program. At that time, the animal numbers and corresponding body weights will be entered into the WIL Toxicology Data Management System (WTDMS). A printout containing the animal numbers and individual group assignments will be generated based on body weight stratification into a block design. Animals will then be arranged into the groups according to the printout. The control group and three test item groups will consist of ~~20~~ 25 males and ~~20~~ 25 females each.

Any animal assigned to the study that is found dead, euthanized *in extremis* or exhibits abnormal clinical signs, reduced food consumption or body weight losses prior to the start of dosing may be replaced by an animal of appropriate age when possible. Replacement animals will be arbitrarily assigned (not computer randomized) to the study based on comparable body weights (if possible) with respect to the animal that was replaced.

7.3 Route and Rationale of Test Item Administration:

The route of administration will be oral (gavage). Historically, this route has been used extensively for studies of this nature. Appropriately sized flexible, Teflon®-shafted, stainless steel dosing cannulae will be used for the oral administration by gavage. The dosing cannulae mayor may not be ball-tipped as appropriate for the age of the animal.~~Appropriately sized flexible, Teflon® shafted, stainless steel balltipped dosing cannulae will be used for the oral administration by gavage~~.

7.4 Organization of Test Groups, Dosage Levels and Treatment Regimen:

7.4.1 Organization of Test Groups:

The dose levels proposed for the current study are 0, 0.1, 0.5, and 5 mg/kg/day and are based on previous and ongoing general toxicity studies in mice. These levels are currently being tested in an ongoing (in-life dosing phase complete) subchronic toxicity 90-day gavage study (DuPont-18405-1307). The doses for the 90-day gavage study were based on results from a previous 28-day gavage study (DuPont-24459) in which doses of 0, 0.1, 3, and 30 mg/kg/day were tested.

The following table presents the study group arrangement.

Group Number	Test Item	Dosage Level (mg/kg/day)	Dosage Concentration (mg/mL)	Dosage Volume (mL/kg)	Number of Animals	
					Male	Female
1	Vehicle Control[b]	0	0	10	25	25
2	H-28548	0.1	0.01	10	25	25
3	H-28548	0.5	0.05	10	25	25

4	H-28548	5	0.5	10	25	25

[a] Dosage levels will be corrected for the purity of 84%.
[b] Deionized Water

7.4.2 Vehicle Control Item:

Deionized Water

7.4.3 F_0 Treatment Regimen:

The test and control items will be administered once daily at approximately the same time each day as follows:

7.4.3.1 Males:

F_0 males will be dosed for a minimum of 70 days prior to mating and continuing until the day prior to the scheduled euthanasia.

7.4.3.2 Females:

F_0 females will be dosed for a minimum of 14 days prior to mating and continuing throughout mating, gestation and lactation until Lactation Day (LD) 20, inclusively, for females that deliver, with the exception of the 5 females/group that are selected for blood collection on LD 21, which will also receive a dose on LD 21. ~~F_0 females will be dosed for a minimum of 14 days prior to mating and continuing throughout mating, gestation and lactation until Lactation Day (LD) 21 for females that deliver. For females that do not have positive signs of mating or delivery, dosing will continue until one day prior to euthanasia.~~

7.4.3.3 F_1 Males and Females:

F_1 males and females will be dosed beginning in PND 21 through PND 40, inclusively. ~~F_1 males and females will be dosed beginning in PND 21 until one day prior to euthanasia.~~

7.4.4 Adjustment of Dosages:

Individual dosages will be calculated based on the most recent body weight to provide the proper mg/kg/day dosage.

7.5 Preparation and Analysis of Test Item Formulations:

7.5.1 Method and Frequency of Preparation:

Based on the physical characteristics of the test substance, appropriate methods will be used to ensure the best possible formulations of the test substance in the vehicle. Dosing formulations will be stored refrigerated (2-8°C) for a maximum of 12 days. The Study Director or designee will visually inspect the formulations prior to the initiation of dosing. This visual inspection will be performed to ensure that the formulations are visibly homogeneous and acceptable for dosing. Any special procedures required for formulation will be documented according to Good Laboratory Practices and presented in the final report of this study. Test substance formulations will be prepared approximately weekly and divided into aliquots for daily dispensation. The test substance and vehicle formulations will be stirred continuously during dosing.

7.5.2 Homogeneity, Resuspension Homogeneity, Stability and Concentration Determination of Test Substance Formulations:

Stability and resuspension homogeneity were established on a previous study (Haas, Draft; WIL-189216). Test substance formulations were stable and 12 days of room temperature storage or refrigerated storage (2-8°C) at concentrations of 0.01 mg/mL and 100 mg/mL and homogenous following resuspension after 12 days of refrigerated storage (2-8°C). Stability and resuspension homogeneity will not be conducted on this study.

Homogeneity and concentration will be conducted on the first formulations prepared for dosing. Four 1-mL samples will be collected from the top, middle and bottom of the test substance formulations from the low and high dose groups and the samples analyzed to assess the homogeneity of the test substance in the mixtures; the middle strata will serve as the measure of test substance concentration. Four 1-mL samples will be taken from the middle on the control and the mid-dose groups and analyzed for concentration of the test substance.

Concentration will be assessed on Week 4, 8, 12, 16 and 19 formulations prepared for dosing. Four 1-mL samples will be collected from the middle of each test substance formulation and the control group and analyzed for test substance content.

7.5.3 Sample Analysis:

Samples will be transferred to the Analytical Chemistry Department at WIL Research Laboratories, LLC for analysis. Analyses of test article formulations will be performed using a method developed and validated

by WIL Research Laboratories, LLC. Initially, two of each set of four replicate, 1-mL samples will be analyzed; the remaining two 1-mL samples will be stored frozen (approximately -20°C) at WIL and will function as back-up samples. Back-up samples will be analyzed if requested by the Sponsor or Study Director or may be discarded following results that are within specifications and approval of the Study Director.

7.6 F_0 Breeding:

After a minimum of 70 days for males and 14 days of exposure for females, of exposure, one female will be cohabitated with one male mouse of the same treatment group, avoiding sibling mating, in a plastic cage for mating. Detection of mating will be confirmed by ~~evidence of sperm in the vaginal lavage~~the appearance of a vaginal copulatory plug. After confirmation of mating, the female will be returned to an individual plastic cage and the day will be designated as day 0 of gestation.

A maximum of 14 days will be allowed for mating. After 14 days of mating, any females who have not shown evidence of breeding will be placed in a plastic cage containing nesting material.

7.7 F_0 Parturition and Lactation and F_1 Litters:

The day parturition is initiated will be designated as day 0 of lactation. Any difficulties at the time of parturition will be recorded. When parturition is judged to be complete, the sex of each pup will be determined, pups will be examined for gross malformations and the number of stillbirths and live pups will be recorded. Any changes or abnormalities in nesting and nursing behavior will be recorded. The dam and litter will remain together until postnatal day (PND) 21.

7.8 Identification of F_1 Litters:

Upon completion of delivery, all pups will be individually identified by tattoo markings applied to the digits. To reduce variability among the litters, on PND 4, eight pups of equal sex distribution (if possible) from each litter will be randomly selected. For litters consisting of fewer than eight pups, adjustments for litter sizes will not be performed. Following selection, the non-selected PND 4 pups will be euthanized by an intraperitoneal injection of sodium pentobarbital and discarded.

7.9 General Observations During the Experimental Period

7.9.1 Parental Appearance and Behavior:

Each parental mouse (F_0) will be observed twice daily for moribundity and mortality, once in the morning and once in the afternoon. A detailed physical examination will be conducted weekly. Mortality and all signs of overt toxicity will be recorded on the day observed. The observations shall include, but are not limited to, evaluations for changes in appearance of the skin and fur, eyes and mucous membranes, respiratory, circulatory, autonomic and central nervous systems, somatomotor activity and behavior. During the period of expected parturition, the dams will be observed twice daily for dystocia, prolonged labor, delayed labor or other difficulties at parturition. All animals will also be observed on the day of necropsy and findings will be recorded.

During the treatment period, each animal will be observed at approximately 1-2 hours following each dose administration for findings that are potentially related to treatment of that might change before the next scheduled observation. Additional post dosing observation periods may be necessary and will be documented in the study records.

7.9.2 Parental Body Weights:

All animals will have a final body weight recorded on the day of euthanasia.

7.9.2.1 Males:

Recorded individually on a weekly basis, beginningon the first day of dose administration, until euthanasia.

7.9.2.2 Females:

For those females with evidence of mating, body weights will be recorded individually on a weekly basis, beginningon the first day of dose administration, until evidence of copulation is observed and on gestation days 0, 4, 7, 11, 14 and18 and on lactation days 1, 4, 7, 14 and 21~~Recorded individually on a weekly basis, beginning on the first day of dose administration, until evidence of copulation is observed and on gestation days 0, 4, 7, 11, 14, 17 and 20and lactation days 1, 4, 7, 14 and 21.~~

For females with no evidence of mating, individualbody weights will continue to be recorded on a weekly basis until euthanasia.

7.9.3 Parental Food Consumption*:

Individual food consumption will not be recorded during the breeding period because the animals are cohabitated at that time.

7.9.3.1 Males:

Recorded individually on a weekly basis, beginning on the first day of dose administration, until euthanasia.

7.9.3.2 Females:

Recorded individually on a weekly basis beginning on the first day of dose administration, until the start of the mating period. Individual food consumption will be recorded on the day evidence of copulation is observed (GD 0) and on gestation days 4, 7, 11, 14 and 18 and lactation days 1, 4, 7, 14 and 21. ~~Recorded individually on a weekly basis beginning on the first day of dose administration, until the start of the mating perid. Individual food consumption will be recorded on the day evidence of copulation is observed (GD 0) and on gestation days 4, 7, 11, 14, 17 and 20 and lactation days 1, 4, 7, 14 and 21.~~

For females with no evidence of mating, individual food consumption will continue to be recorded on a weekly basis following the end of the mating period until euthanasia.

7.9.4 Examination of Offspring:

7.9.4.1 Appearance and Behavior:

All pups will be observed daily for general appearance and behavior and survival during lactation. A detailed physical examination will be recorded for each pup on PND 1,4, 7, 14 and 21. Any abnormalities in nesting and nursing behavior will be recorded. The pups will be sexed on PND 0, 4, 14 and 21.

7.9.4.2 Body Weights:

Each pup will be weighed on PND 1, 4, 7, 14 and 21.

7.9.5 Pup Deaths:

7.9.5.1 Pups 0 to 4 Days of Age:

Moribund pups will be euthanized by an intraperitoneal injection of sodium pentobarbital. Stillborn pups, pups found dead between birth and PND 4, and any pups that are euthanized *in extremis* will be dissected (including the heart and the brain examined by a mid-coronal slice) by a technique described by Stuckhardt and Poppe (Stuckhardt and Poppe, 1984). If a skeletal anomaly is suspected, the pups will be eviscerated, cleared and stained with Alizarin Red S as described by Dawson (Dawson, 1926) and examined. Representative specimens with malformations may be preserved in 10% neutral buffered formalin at the discretion of the study director.

7.9.5.2 Pups 5 Days of Age to Weaning:

Moribund pups will be euthanized by an intraperitoneal injection of sodium pentobarbital (prior to PND 11) or by carbon dioxide inhalation. A gross necropsy will be performed on pups found dead or euthanized *in extremis*, and gross lesions will be saved for possible future histopathological examination in 10% neutral buffered formalin. If a skeletal anomaly is suspected, the pups will be eviscerated, cleared and stained with Alizarin Red S as described by Dawson (Dawson, 1926) and examined.

7.10 Selection of F_1 Generation and Termination of PND 21 Nonselected Pups:

One male and one female pup per litter will be selected for the F_1 generation on or prior to PND 21. Only pups not expected to survive due to notable physical limitations will not be available for selection. A detailed evaluation of each pup excluded from selection will be recorded.

All PND 21 pups not selected for the F_1 generation will be euthanized by carbon dioxide inhalation. A gross necropsy examination will be performed with an emphasis on evaluation of developmental morphology and organs of the reproductive system. Any gross lesions will be saved for possible future histopathological examination in 10% neutral buffered formalin.

7.11 Euthanasia of F_0 Generation:

7.11.1 Females:

7.11.1.1 Females Which Deliver:

On lactation day 21, all F_0 females that delivered will be euthanized by carbon dioxide inhalation. A gross examination will be performed and tissues preserved as described in Section 8.1. The number of former implantation sites willbe recorded. Organ weights will be collected and tissues preserved as described in Section 8.2.

7.11.1.2 Females Which Fail to Deliver:

On post-mating day 23 (females with evidence of mating) or post-cohabitation day 23 (females without evidence of copulation), the F_0 females which fail to deliver will be euthanized by carbon dioxide inhalation. ~~On post-mating day 25 (females with evidence of copulation) or postcohabitation day 25 (females without evidence of copulation), the F_0 females which fail to deliver will be euthanized by carbon dioxide inhalation.~~ A gross necropsy examination will be performed and tissues will be preserved as described in Section 81. Organ weights will be collected as described in Section 82 with the exception of any ammonium sulfide stained uterus, which will be discarded. Uteri which appear nongravid by macroscopic examination will be opened and placed in a 10% ammonium sulfide solution (Salewski, 1964) for detection of early implantation loss.

7.11.1.3 Females with Total Litter Loss:

Females with total litter loss will be euthanized by carbon dioxide inhalation on the same day. The number offormer implantation sites will be recorded and the numberof corpora lutea (if litter loss occurs on or before PND 4) will be recorded. A gross necropsy examination will be performed and tissues preserved as described in Section 8.1. Organ weights will be collected as described in Section 8.2.

7.11.1.4 F_0 Deaths and Animals Euthanized *in Extremis*:

Females not surviving until the scheduled euthanasi will have a gross necropsy examination performed and tissues preserved as described in Section 8.1. Animals not expected tosurvive to the next observation period (moribund) will be euthanized by carbon

dioxide inhalation and have a gross necropsy examination performed and tissues preserved as described in Section 8.1. Organ weights will not be collected from found dead or euthanized *in extremis* females. The number and location of implantation sites or scars will be recorded for females dying or euthanized during gestation and lactation. The number of corpora lutea will be recorded for females dying or euthanized during gestation and up to and including lactation day 4. Uteri which appear nongravid by macroscopic examination will be opened and placed in a 10% ammonium sulfide solution (Salewski, 1964) for detection of early implantation loss.

Viable fetuses will be euthanized by an intrathoracic injection of sodium pentobarbital. Recognizable fetuses will be examined externally for gross abnormalities. Representative specimens with malformations may be preserved in 10% neutral-buffered formalin, at the discretion of the study director. For females found dead or euthanized *in extremis* during lactation, all pups will be examined externally and subjected to a necropsy examination according to Section 7.9.5.

7.11.2 Males:

Following completion of the mating period, all F_0 males will be euthanized by carbon dioxide inhalation and subjected to a gross necropsy and tissue preservation as described in Section 8.1. Organ weights will be collected as described in Section 8.2.

Males not surviving until the scheduled euthanasia will be subjected to a gross necropsy and tissue preservation as described in Section 8.1. Any males not expected to survive to the next observation period (moribund) will be euthanized by carbon dioxide inhalation and also necropsied and have tissues preserved as described in Section 8.1. Organ weights will not be collected.

7.12 F_1 Generation General Observations During The Experimental Period:

7.12.1 F_1 Clinical Observations:

Following weaning and selection, the mice will be observed twice daily for moribundity and mortality, once in the morning and once in the afternoon. ~~Clinical observations will be recorded daily~~A detailed physical examinations will be conducted weekly. Mortality and all signs of overt toxicity will be recorded on the day observed. The observations shall include, but are not limited to, evaluation for changes in

appearance of the skin and fur, eyes, mucous membranes, respiratory, circulatory, autonomic and central nervous system function, somatomotor activity and behavior patterns. All animals will also be observed on the day of necropsy and any findings will be recorded.

During the treatment period, each animal will be observed at approximately 1-2 hours following each dose administration for findings that are potentially related to treatment of that might change before the next scheduled observation. Additional post dosing observation periods may be necessary and will be documented in the study records.

7.12.2 F_1 Body Weights and Food Consumption:

F_1 males and females will be have a body weight recorded approximately weekly, beginning with the start of test ~~diet~~ substance administration until euthanasia (PND 21, 28, 35 and 40). All animals will have a final body weight recorded on the day of euthanasia.

F_1 males and females will have food consumption recorded individually on an approximately weekly basis beginning on PND 28 until euthanasia (PND 28, 35 and 40). Food consumption will not be collected from PND 21 to PND 28 during group housing for the F_1 males and females.

7.13 F_1 Postweaning Developmental Landmarks:

Offspring selected for the F_1 generation will be evaluated for attainment of the following landmarks of sexual maturity:

7.13.1 Balanopreputial Separation:

Each male pup will be observed for balanopreputial separation beginning on PND 25 as described by Korenbrot *et al.* (Korenbrot 1977). Examination of the males will continue daily until balanopreputial separation is present. The body weight of each male will be recorded on the day of attainment of balanopreputial separation.

7.13.2 Vaginal Patency:

Each female pup will be observed for vaginal patency beginning on PND 21 (only those selected for the F_1 generation) as described by Adams *et al.* (Adams 1985). Examination of the females will continue daily until vaginal patency is present. The body weight of each female will be recorded on the day of attainment of vaginal patency.

7.14 Euthanasia of F_1 Generation:

7.14.1 Scheduled Necropsy

On PND 40, all F_1 animals will be euthanized by carbon dioxide inhalation. A gross necropsy examination will be performed with an emphasis on evaluation of developmental morphology and organs of the reproductive system. Any gross lesions will be saved for possible future histopathological examination in 10% neutral buffered formalin.

7.14.2 Unscheduled Deaths or Animals Euthanized *in Extremis*

Any F_1 animals not surviving until the scheduled euthanasia or not expected to survive to the next observation period (euthanized by carbon dioxide inhalation) will be necropsied. A gross necropsy examination will be performed with an emphasis on evaluation of developmental morphology and organs of the reproductive system. Any gross lesions will be saved for possible future histopathological examination in 10% neutral buffered formalin.

7.15 Plasma Sample Collection and Analysis:

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7.15.1 Interval:

Blood samples will be collected at 2 hours post dose administration on LD 21 at necropsy from 5 randomly selected F_0 females per group that delivered. A blood sample will be collected from all females that failed to deliver on post-mating day 23 at the time of the scheduled necropsy (not timed).

In addition, all control females that delivered but were not selected for blood collection as indicated above, will have blood samples taken on LD 21 at the time of scheduled necropsy (not timed) to provide control animal plasma for method development work to be conducted by the Sponsor. These control samples will be processed and shipped as described for the study samples.

Blood samples will also be collected from the F_1 culled pups on PND 4 from 10 randomly chosen litters in each group following culling and data collection.

On PND 21, blood samples will be collected from 5 randomly selected F_1 males and females in each group at the time of the scheduled necropsy (not timed) that are not selected for the $_1$ generation.

On PND 40, blood samples will be collected at 2 hours dose administration at necropsy from 5 randomly selected F_1 males and females in each group.

7.15.2 Route of Collection:

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Blood samples will be collected via the vena cava following euthanasia by carbon dioxide inhalation from the F_0 females and the F_1 PND 21 and PND 40 animals.

Blood samples will be collected via decapitation from the PND 4 pups and pooled by litter.

7.15.3 Target Blood Volume:

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For the F_0 females and the F_1 PND 21 and PND 40 animals, 1.0 mL or as much as possible, will be collected into pre-chilled, uniquely-labeled tubes. For the PND 4 pups, blood will be pooled by litter from all the culled pups in each litter to obtain as much blood as possible.

7.15.4 Anticoagulant:

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K_3EDTA

7.15.5 Sample Handling and Plasma Preparation:

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Samples will be kept on wet ice, protected from light, until centrifugation. All samples will be centrifuged [approximately 3000 rpm (approximately 2060 x g) for approximately 10 min] at approximately 4°C. Plasma will be transferred into new, uniquely-labeled polypropylene tubes.

7.15.6 Label Information:

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Samples will include study number, dose group, animal number, interval, sample type and date and time of blood collection.

7.15.7 Storage:

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Plasma samples will be stored frozen at approximately -20°C until analysis. The time and date the samples were placed in the freezer will be recorded.

7.15.8 Sample Shipment:

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Frozen samples in dry ice, an inventory list and documentation of actual blood collection times for each animal will be shipped on the first Monday or Tuesday after the last sample is collected. The recipient will be notified at least 24 hours in advance of any shipment. Samples will be shipped overnight to:

Michael Mawn, PhD
Senior Research Chemist
DuPont Stine-Haskell Research Center
1090 Elkton Road
Bldg. S-315 Lab 1334
Newark, DE 19714-0030
Tel: 302-451-3365
Email: michael.p.mawn@usa.dupont.com

7.15.9 Plasma Analyses and Report:

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Plasma samples will be analyzed for the test article content after solvent protein precipitation with LC/MS/MS analysis. The method of analysis will be documented in the study records and final report. The Principal Investigator for the plasma analysis will be responsible for all bioanalytical delegated-phase activities and will issue a formal bioanalytical/plasma analyses report from the data generated that will be included as an appendix in the final report. A Quality Assurance and GLP compliance statement signed by Sponsor and archival location of the data will be provided to the WIL Study Director for inclusion in the Final Report.

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8 ANATOMIC PATHOLOGY:

8.1 Macroscopic Examination:

A complete necropsy will be conducted on all F_0 parental animals dying spontaneously, euthanized *in extremis* (by carbon dioxide inhalation) or at termination. This will include examination of the external surface, all orifices, the cranial cavity, the external surface of the brain and the thoracic, abdominal

and pelvic cavities including viscera. For F_0 females, the number of former implantation sites will be recorded.

At the time of necropsy, the following tissues and organs will be collected and placed in 10% neutral-buffered formalin (except as noted):

Coagulating gland	Prostate
Kidneys (2)	Seminal vesicles (2)
Liver	Testes with epididymides (2)[a]
Mammary gland (females only)	and vas deferens
Ovaries and oviduct (2)	Uterus[b] with cervix and vagina
Pituitary	All gross lesions[c]

a - Testes and epididymides will be fixed in Bouin's solution. Care will be taken to ensure separation between the left and right organs

b - Any uterus stained in 10% ammonium solution for detection of implantation sites will be discarded and will not be preserved in 10% neutral buffered formalin.

c - Representative sections of corresponding organs from a sufficient number of controls will be retained for comparison, if possible.

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8.2 Organ Weights:

The following organs will be weighed from all F_0 parental animals euthanized at scheduled termination. Organ-to-final-body weight and organ-to-brain weight ratios will be evaluated.

Brain	Ovaries (with oviducts)
Epididymides*	Pituitary
Kidneys	Testes*
Liver	

* - These paired organs will be weighed separately.

8.3 Microscopic Examination:

Microscopic examination of hematoxylin-eosin stained paraffin sections will be performed on the listed tissues from all F_0 parental animals from the control and high-dose groups and from all parental animals dying spontaneously or euthanized *in extremis* and from any animals in the low and mid dose groups with impaired fertility (males that did not sire a litter or females that did not deliver a litter). ~~Microscopic examination of hematoxylin-eosin stained paraffin sections will be performed on the following tissues from all F_0 parental animals from the control and high-dose groups and from all parental animals dying spontaneously or euthanized *in extremis*.~~ If a target organ is identified in the high-dose group, this organ will be examined from all animals in the low and mid-dose groups (at additional cost):

Cervix	Seminal vesicles

Coagulating gland	Testes
Epididymides	Uterus
Ovaries and oviduct	Vagina
Prostate	All gross (internal) lesions

The slides will be prepared by WIL Research Laboratories, LLC and then shipped to Sponsor at the address and contact below for examination by the Principal Investigator, Pathology.

Carolyn Lloyd
DuPont Haskell Global Centers for Health & Environmental Sciences
Investigative Sciences, S320/531
1090 Elkton Road
Newark, DE 19714-0050
Tel: 302-366-5401
Fax: 302-451-4530
Email: carolyn.w.lloyd@usa.dupont.com

The examination of the slides will be performed bythe Principal Investigator for Pathology. A final pathology report will be prepared and submitted to WIL Research for inclusion as an appendix in the main study final report. A Quality Assurance and GLP compliance statement signed by the performing laboratory will be provided to the WIL Study Director for inclusion in the Final Report. The Sponsor is responsible for archiving of raw data associated with the conduct of the pathological examination.

9 DURATION OF STUDY:

The two generations to be studied (parental animals and first generation offspring) will be termed F_0 and F_1, respectively. The conduct of this study will require approximately 22 weeks for acclimation, mating, gestation and lactation of the F_0 generation.

10 STATISTICAL METHODS:

All analyses will be two-tailed for significance levels of 5% and 1%. All means will be presented with standard deviations. All statistical tests will be performed by a computer with appropriate programming as referenced below. The litter, rather than the pup, will be considered as the experimental unit.

10.1 Parental In-Life Data:

Continuous data variables [mean body weights, body weight gains and food consumption at each interval], pre-coital intervals, gestation length, former implantation sites, unaccounted-for sites, mean days of attainment of

developmental landmarks (balanopreputial separation and vaginal patency) and the body weight on the day of attainment will be subjected to a parametric one-way analysis of variance (ANOVA) (Snedecor, 1980) to determine intergroup difference. If the results of the ANOVA are significant ($p<0.05$), Dunnett's test (Dunnett, 1964) will be applied to the data to compare the treated groups to the control group.

Male and female mating, fertility, copulation and conception indices of the treated groups will be compared to the control group using the Chi-square test with Yates' correction factor (Hollander, 1999).

10.2 Litter Data:

The mean litter proportions (% per litter) of pup viability during the postnatal period and sex ratio at birth will be subjected to the Kruskal-Wallis nonparametric ANOVA test (Kruskal, 1952) to determine intergroup difference. If the results of the ANOVA are significant ($p<0.05$), the Dunn's Test (Dunn, 1964) will be applied to compare the treated groups to the control group. Mean numbers of pups born, live litter size and litter weights will be subjected to the parametric ANOVA test (Snedecor, 1980) and Dunnett's test (Dunnett, 1964) as described above with the litter representing the experimental unit.

10.3 Histopathology and Organ Weight Data:

Histopathological findings of each treated group will be compared to those of the control group by the Fisher's Exact test (Steel, 1980). Organ weights (absolute and relative to body weights and relative to brain weights) will be subjected to a parametric ANOVA test (Snedecor, 1980) and Dunnett's test (1964) as described above.

11 QUALITY ASSURANCE:

The study will be audited by the WIL Quality Assurance Unit while in progress to assure compliance with the study protocol and protocol amendments, WIL Standard Operating Procedures and the appropriate provisions of EPA/TSCA and FIFRA Good Laboratory Practice Standards published in the Federal Register (40 CFR Part 792 and 40 CFR Part 160) and the OECD Principles of Good Laboratory Practice. The final report will be audited by the WIL Quality Assurance Unit prior to submission to the Sponsor Representative to assure that the final report accurately describes the conduct and the findings of the study.

The plasma samples analysis and the pathological examination of the slides will be conducted following the Standard Operating Procedures of the performing laboratory and in accordance with GLPs.~~The pathological examination of the slides will be conducted following the Standard Operating Procedures of the performing laboratory and in accordance with GLPs.~~ Quality Assurance monitoring of these analyses for SOP and GLP compliance is the responsibility of the performing laboratory. Inspection reports will be supplied to the Study Director. Upon completion of the prescribed activities and submission of the results to the Sponsor and Study Director the performing laboratory will provide a signed Quality Assurance Statement to the Sponsor (copy to the Study Director). The results will be included in the final report.

This study will be included on the WIL master list of regulated studies.

12 RECORDS TO BE MAINTAINED:

All original raw data records, as defined by WIL SOPs and the applicable GLPs, will be stored as described in Section 13 in the Archives at WIL Research Laboratories, LLC.

The Sponsor will be responsible for the archival of the raw data and records for the plasma sample analyses and the pathological examination.~~The Sponsor will be responsible for the archival of the raw data and records for the pathological examination.~~

13 WORK PRODUCT:

The Sponsor will have title to all documentation records, raw data, slides, specimens and other work product generated during the performance of the study. Any remaining plasma samples and formulation samples will be discarded after the issuance of the Final Report. ~~Any remaining formulation samples will be discarded after the issuance of the Final Report.~~ All work product, including raw paper data, pertinent electronic storage media and specimens, will be retained for a period of six months following issuance of the final report in the Archives at WIL Research Laboratories, LLC. Thereafter, WIL Research Laboratories, LLC will charge a monthly archiving fee for retention of all work product. All work product will be stored in compliance with regulatory requirements.

Any work product, including documents, specimens, and samples, that are required by this protocol, its amendments, or other written instructions of the Sponsor, to be shipped by WIL Research Laboratories, LLC to another location will be appropriately packaged and labeled as defined by WIL's SOPs and delivered to a common carrier for shipment. WIL Research Laboratories, LLC will not be responsible for shipment following delivery to the common carrier.

All work product generated at a performing laboratory will be retained at an appropriate archive facility as designated by the SOPs of the performing laboratory.

14 REPORTS:

The final report will contain a summary, test item data, methods and procedures, maternal and pup data WIL Historical Control Data, the analytical chemistry report, the plasma analysis report, the pathology report and an interpretation and discussion of the study results. ~~The final report will contain a summary, test item data, methods and procedures, maternal and pup data WIL Historical Control Data, the analytical chemistry report, pathology report and an interpretation and discussion of the study results.~~ The final report will be comprehensive and shall define level(s) inducing toxic effects as well as no-effect level(s) under the conditions of this investigation. The report will contain all information necessary to conform with current OPPTS and OECD specifications.

WIL Research Laboratories, LLC will submit one copy of an audited draft report in a timely manner upon completion of data collection prior to issuance of the final report. One revision will be permitted as part of the cost of the study, from which the Sponsor's reasonable revisions and suggestions will be incorporated into the final report, as appropriate. Additional changes or revisions may be made, at extra cost. It is expected that the Sponsor will review the draft report and provide comments to WIL Research Laboratories, LLC within a two-month time frame following submission. WIL Research Laboratories, LLC will submit the final report within one month following receipt of comments. If the Sponsor's comments and/or authorization to finalize the report have not been received at WIL Research Laboratories, LLC within one year following submission of the draft report, WIL Research Laboratories, LLC may elect to finalize the report following appropriate written notification to the Sponsor. Two electronic copies (PDF) of the final report on CD-R will be provided. Requests for paper copies of the final report may result in additional charges.

15 ANIMAL WELFARE ACT COMPLIANCE:

This study will comply with all applicable sections of the Final Rules of the Animal Welfare Act (AWA) regulations (9 CFR Parts 1, 2 and 3). The Sponsor should make particular note of the following:

The Sponsor Representative's signature on this protocol documents for the Study Director the Sponsor's assurance that the study described in this protocol does not unnecessarily duplicate previous experiments.

Whenever possible, procedures used in this study have been designed to avoid or minimize discomfort, distress or pain to animals. All methods are described in this study protocol or in written laboratory Standard Operating Procedures.

Animals that experience severe pain or distress that cannot be relieved will be painlessly euthanized as deemed appropriate by the veterinary staff and Study Director. The Sponsor will be advised by the Study Director of all circumstances which could lead to this action in as timely a manner as possible.

Methods of euthanasia used during this study are in conformance with the above-referenced regulation.

The Sponsor/Study Director has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and has provided a written narrative description (AWA covered species) of the methods and sources used to determine that alternatives are not available.

16 PROTOCOL MODIFICATION:

Modification of the protocol may be accomplished during the course of this investigation. However, no changes will be made in the study design without the verbal or written permission of the Sponsor. In the event that the Sponsor verbally requests or approves a change in the protocol, such changes will be made by appropriate documentation in the form of protocol amendment. All alterations of the protocol and reasons for the modification(s) will be signed by the Study Director and the Sponsor Representative.

17 REFERENCES:

Adams, J.; Buelke-Sam, J.; Kimmel, C.A.; Nelson, C.I.; Reiter, L.W.; Sobotka, T.J.; Tilson, H.A.; Nelson, B.K. Collaborative behavioral teratology study: protocol design and testing procedure. *Neurobehavioral Toxicology and Teratology* **1985,** *7,* 579-586.

Dawson, A.B. A note on the staining of the skeleton of cleared specimens with Alizarin Red S. *Stain Technology* **1926,** *1,* 123-124.

Dunn, O.J. Multiple comparisons using rank sums *Technometrics* **1964,** *6(3),* 241-252.

Dunnett, C.W. New tables for multiple comparisons with a control. *Biometrics* **1964,** *20,* 482-491

Haas, M. A 90-Day Oral (Gavage) Study of H-28548 in Rats with a 28-Day Recovery. WIL-189216, **Draft.**

Hollander, M.; Wolfe, D.A. *Nonparametric Statistical Methods,* 2nd ed.; Hollander, M., Wolfe, D.A., Eds.; John Wiley and Sons, Inc.: New York, NY, **1999;** p 468.

Korenbrot, C.C.; Huhtaniemi, I.T.; Weiner, R.W. Preputial separation as an external sign of pubertal development in the male rat. *Biology of Reproduction* **1977,** *17,* 298-303.

Kruskal, W.H.; Wallis, W.A. Use of ranks in one-criterion variance analysis. *Journal of the American Statistical Association* **1952,** *47,* 583-621.

Salewski, E. Färbemethode zum makroskopischen Nachweis von Implantationsstellen am Uterus der Ratte. [Staining method for a macroscopic test for implantation sites in the uterus of the rat]. *Naunyn - Schmiedebergs Archiv für Experimentelle Pathologie und Pharmakologie* **1964,** *247,* 367.

Snedecor, G.W.; Cochran, W.G. One Way Classifications; Analysis of Variance. In *Statistical Methods,* 7th ed.; The Iowa State University Press: Ames, IA, **1980;** pp 215-237.

Steel, R.G.D.; Torrie, J.H. *Principles and Procedures of Statistics, A Biometrical Approach,* 2nd ed.; McGraw-Hill Book Company: New York, NY, **1980;** pp 504-506.

Stuckhardt, J.L.; Poppe, S.M. Fresh visceral examination of rat and rabbit fetuses used in teratogenicity testing. *Teratogenesis, Carcinogenesis and Mutagenesis* **1984,** *4,* 181-188.

18 PROTOCOL APPROVAL:

Sponsor approval received via _____ on _____.
Date

E. I. du Pont de Nemours and Company

_____ _____
Susan M. Munley, MA Date
Sponsor Representative

WIL Research Laboratories, LLC

_____ _____
Tammye L. Edwards, BS, LAT Date
Study Director

_____ _____
Donald G. Stump, PhD, DABT Date
Director, Developmental and
Reproductive Toxicology

From: Jane Bradd Andersen <JANE-BRADD.ANDERSEN@usa.dupont.com>
To: Rose Allison/DC/USEPA/US@EPA
Subject: Re: Review and approval of Respirators
Submit Time: 6/1/2010 21:50:20

Rose,

Per our discussion this afternoon....

Kind regards,

Jane Bradd-Andersen
tel:302-999-2377
fax:302-999-2177
jane-bradd.andersen@usa.dupont.com

Jane Bradd Andersen/AE/DuPont

04/28/2010 11:58 AM

To "Allison Rose" <Allison.Rose@epamail.epa.gov>

cc

Subject Re: Review and approval of Respirators Link

Thanks Rose. I really appreciate your help. Have a great week.
Kind regards,
Jane
Office: 302-999-2377
Cell: Personal Phone / Ex. 6
sent from my Blackberry Wireless Handheld

----- Original Message -----
From: Allison.Rose
Sent: 04/28/2010 11:49 AM AST
To: Jane Bradd Andersen
Subject: Re: Review and approval of Respirators

Hi Jane, I think so but I can have our Chem e and IH confirm. It might take awhile. Talk with you in a week or so. Rose

---

Rose Allison For Deliveries

Team Leader **EPA East Building**
New Chemicals Program *1201 Constitution Ave NW *
Chemical Control Division (7405M) **Room 4419G**
US EPA **Wash DC
20004**
1200 Pennsylvania Ave. NW
Washington, DC 20460
202/564-8970/FAX 202/564-9490

From: Jane Bradd Andersen <JANE-BRADD.ANDERSEN@usa.dupont.com>

To: Rose Allison/DC/USEPA/US@EPA

Date: 04/28/2010 11:19 AM

Subject: Review and approval of Respirators

Hi Rose.

Last year we discussed the Respirator Cartridge Data submitted in the PMNs for P-08-508 and P-08-509 [Attachment 125, pgs 1759 -1760]. In the Consent Order for the two PMN substances section for New Chemical Exposure Limit subsection (e) Respiratory Protection (2) Selection of Appropriate Respirator Protection (pages 30-32), on page 30 the Consent Order, it states "After the Company has conducted exposure monitoring in accordance with subsection (d) of this New Chemical Exposure Limit Section..." the Company can select respiratory protection which corresponds to the included table. Specifically on page 31, it states "If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA".

My question to you, has the Cartridge Service Life Testing data supplied in Attachment 125 of the PMN been reviewed by the Agency and does DuPont have approval from the Agency to use the respirators outlined in Attachment 125 in a way that corresponds to the respirator cartridge selection outlined in the tabled on pages 31 and 32 of the Consent Order.

Have a good week. We can chat when I get back from vacation the week of May10th.

Kind regards,

Jane Bradd-Andersen
tel:302-999-2377
fax:302-999-2177
jane-bradd.andersen@usa.dupont.com

This communication is for use by the intended recipient and contains information that may be Privileged, confidential or copyrighted under applicable law. If you are not the intended recipient, you are hereby formally notified that any use, copying or distribution of this e-mail, in whole or in part, is strictly prohibited. Please notify the sender by return e-mail and delete this e-mail from your system. Unless explicitly and conspicuously designated as "E-Contract Intended", this e-mail does not constitute a contract offer, a contract amendment, or an acceptance of a contract offer. This e-mail does not constitute a consent to the use of sender's contact information for direct marketing purposes or for transfers of data to third parties.

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http://www.DuPont.com/corp/email_disclaimer.html

Submit Time: 4/5/2010 19:57:23
From: CN=Rose Allison/OU=DC/O=USEPA/C=US
To: CN=Rebecca Jones/OU=DC/O=USEPA/C=US@EPA
Cc:
Subject: Fw: TSCA 8e Letter - P-08-509

fyi 8(e)

Rose Allison
202/564-8970/FAX 202/564-9490

----- Forwarded by Rose Allison/DC/USEPA/US on 04/05/2010 03:56 PM -----

From: Mike Kaplan <Mike.Kaplan@USA.dupont.com>

To: Rose Allison/DC/USEPA/US@EPA

Cc: Jane Bradd Andersen <JANE-BRADD.ANDERSEN@usa.dupont.com>, James R Hoover <James.R.Hoover@USA.dupont.com>, Mike Kaplan <Mike.Kaplan@USA.dupont.com>

Date: 02/23/2010 08:36 AM

Subject: TSCA 8e Letter - P-08-509

Dear Rose Allison,

Per Jane Bradd Andersen's request, attached is a copy of the letter for P-08-509.

Sincerely,

Mike

A.Michael Kaplan, Ph.D.
Director - Regulatory Affairs
DuPont Haskell Global Centers for Health & Environmental Sciences
1090 Elkton Road
P.O. Box 50
Newark, DE 19714
302-366-5260 Phone
302-451-4531 Fax
mike.kaplan@usa.dupont.com

(See attached file: 2-5-10 FRD-902 2010-033 Letter.pdf)

not constitute a contract offer, a contract amendment, or an acceptance of a contract offer. This e-mail does not constitute a consent to the use of sender's contact information for direct marketing purposes or for transfers of data to third parties.

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2-5-10 FRD-902 2010-033 Letter.pdf 2-5-10 FRD-902 2010-033 Letter.pdf

Limited Permission to Disclose Agreement ("Agreement")

E. I. DuPont de Nemours and Company ("Company") desires to allow the **United States Environmental Protection Agency ("USEPA") / Office of Pollution Prevention and Toxics ("OPPT")** to share certain data and insights relating to Premanufacture Notification ("PMN") substances **P-08-508** and **P-08-509** with the **West Virginia Department of Environmental Protection ("WVDEP")** and the **West Virginia Department of Health and Human Resources ("WVDHHR")** for the purpose of facilitating WVDEP's and WVDHHR's review of the PMN substances for environmental permitting purposes.

Accordingly, by signing below, DuPont authorizes USEPA/OPPT to disclose only the following information to the staff of the WVDEP and the WVDHHR solely for the purpose of facilitating their review of the PMN substances for environmental permitting purposes:

- Copies of any information provided by DuPont to USEPA/OPPT pertaining to PMN substances P-08-508 and P-08-509

- Evaluation reports or other materials produced by USEPA/OPPT pertaining to PMN substances P-08-508 and P-08-509

PMN file:

- Non-confidential chemical identities: Perfluorinated Aliphatic Carboxylic Acid and Perfluorinated Aliphatic Carboxylic Acid, Ammonium Salt

- USEPA/OPPT file numbers: P-08-508 and P-08-509
- Date PMNs received by the USEPA: June 30, 2008

DuPont and USEPA/OPPT acknowledge and agree to the following with respect to this limited permission to disclose:

1. The permission authorized is a limited one. The permission is provided solely to facilitate the review of the PMN substances by the WVDEP and WVDHHR for environmental permitting purposes. USEPA/OPPT agrees to disclose only the information described above.

2. DuPont authorizes the USEPA/OPPT PMN review team to robustly discuss all information in the PMN files in a conference call between the USEPA/OPPT PMN review team personnel, WVDEP personnel, and WVDHHR personnel at a date and time to be determined.

3. This permission is not, therefore, a general waiver of either substantive or procedural confidential business information (CBI) protections under applicable law.

4. DuPont recognizes that the USEPA/OPPT makes no representation as to the level of security or the procedural or substantive rights that information might be afforded once the information is disclosed to WVDEP and WVDHHR.

5. USEPA/OPPT will, however, inform the participating WVDEP and WVDHHR personnel of the existence of any information claimed as confidential or proprietary by DuPont and treated as confidential by the USEPA/OPPT, at the time of disclosure.

6. DuPont, furthermore, makes this limited disclosure with the understanding and belief that WVDEP and WVDHHR will give any information claimed as confidential or proprietary by DuPont and treated as confidential by the USEPA/OPPT all protections to which it is entitled under applicable laws.

7. DuPont acknowledges that there may be materials in the USEPA/OPPT PMN files that may not be shared with WVDEP and WVDHHR. If this situation occurs, USEPA/OPPT will advise WVDEP, WVDHHR, and DuPont what, if any, materials were withheld and why.

8. DuPont furthermore authorizes the transmission of data electronically (e-mail, telephone and/or fax) to WVDEP and WVDHHR for expediting the sharing of information related to the PMN substances. DuPont further authorizes USEPA/OPPT to discuss material in the PMN files with WVDEP and WVDHHR solely for the purpose set forth above.

Agreed and Accepted:

United States Environmental Protection Agency
Office of Pollution Prevention and Toxics

Greg Schweer

Name: GREG SCHWEER

Date: 12/15/2009

Agreed and Accepted:

E. I DuPont de Nemours and Company

James R. Hoover

Name: James R. Hoover

Date: December 10, 2009

Limited Permission to Disclose Agreement ("Agreement")

E. I. DuPont de Nemours and Company ("Company") desires to allow the **United States Environmental Protection Agency ("USEPA") / Office of Pollution Prevention and Toxics ("OPPT")** to share certain data and insights relating to Premanufacture Notification ("PMN") substances **P-08-508** and **P-08-509** with the **West Virginia Department of Environmental Protection ("WVDEP")** and the **West Virginia Department of Health and Human Resources ("WVDHHR")** for the purpose of facilitating WVDEP's and WVDHHR's review of the PMN substances for environmental permitting purposes.

Accordingly, by signing below, DuPont authorizes USEPA/OPPT to disclose only the following information to the staff of the WVDEP and the WVDHHR solely for the purpose of facilitating their review of the PMN substances for environmental permitting purposes:

- Copies of any information provided by DuPont to USEPA/OPPT pertaining to PMN substances P-08-508 and P-08-509

- Evaluation reports or other materials produced by USEPA/OPPT pertaining to PMN substances P-08-508 and P-08-509

PMN file:

- Non-confidential chemical identities: Perfluorinated Aliphatic Carboxylic Acid and Perfluorinated Aliphatic Carboxylic Acid, Ammonium Salt

- USEPA/OPPT file numbers: P-08-508 and P-08-509
- Date PMNs received by the USEPA: June 30, 2008

DuPont and USEPA/OPPT acknowledge and agree to the following with respect to this limited permission to disclose:

1. The permission authorized is a limited one. The permission is provided solely to facilitate the review of the PMN substances by the WVDEP and WVDHHR for environmental permitting purposes. USEPA/OPPT agrees to disclose only the information described above.

2. DuPont authorizes the USEPA/OPPT PMN review team to robustly discuss all information in the PMN files in a conference call between the USEPA/OPPT PMN review team personnel, WVDEP personnel, and WVDHHR personnel at a date and time to be determined.

3. This permission is not, therefore, a general waiver of either substantive or procedural confidential business information (CBI) protections under applicable law.

4. DuPont recognizes that the USEPA/OPPT makes no representation as to the level of security or the procedural or substantive rights that information might be afforded once the information is disclosed to WVDEP and WVDHHR.

5. USEPA/OPPT will, however, inform the participating WVDEP and WVDHHR personnel of the existence of any information claimed as confidential or proprietary by DuPont and treated as confidential by the USEPA/OPPT, at the time of disclosure.

6. DuPont, furthermore, makes this limited disclosure with the understanding and belief that WVDEP and WVDHHR will give any information claimed as confidential or proprietary by DuPont and treated as confidential by the USEPA/OPPT all protections to which it is entitled under applicable laws.

7. DuPont acknowledges that there may be materials in the USEPA/OPPT PMN files that may not be shared with WVDEP and WVDHHR. If this situation occurs, USEPA/OPPT will advise WVDEP, WVDHHR, and DuPont what, if any, materials were withheld and why.

8. DuPont furthermore authorizes the transmission of data electronically (e-mail, telephone and/or fax) to WVDEP and WVDHHR for expediting the sharing of information related to the PMN substances. DuPont further authorizes USEPA/OPPT to discuss material in the PMN files with WVDEP and WVDHHR solely for the purpose set forth above.

Agreed and Accepted:

United States Environmental Protection Agency
Office of Pollution Prevention and Toxics

_____

Name: _____

Date: _____

Agreed and Accepted:

E. I DuPont de Nemours and Company

_____

Name: _____

Date: _____

From: CN=Rose Allison/OU=DC/O=USEPA/C=US
To:
Cc:
Subject: Fw: URGENT ISSUE: 18405-1037 mouse study blood collection amendment -

Hi Jennifer, this must be what the urgent issue was about last Friday...

Rose Allison
Team Leader
New Chemicals Program
Chemical Control Division (7405M)
US EPA
1200 Pennsylvania Ave. NW
Washington, DC 20460
202/564-8970/FAX 202/564-9490

For Deliveries
EPA East Building
*1201 Constitution Ave NW *
Room 4419G
Wash DC 20004

----- Forwarded by Rose Allison/DC/USEPA/US on 05/03/2010 10:57 AM -----

From: James R Hoover <James.R.Hoover@USA.dupont.com>

To: Rose Allison/DC/USEPA/US@EPA

Cc: Gary W Jepson <Gary.W.Jepson-1@USA.dupont.com>, Steven R Frame <Steven.R.Frame@usa.dupont.com>, Susan M Munley <Susan.M.Munley@usa.dupont.com>, Jane Bradd Andersen <JANE-BRADD.ANDERSEN@usa.dupont.com>

Date: 04/30/2010 03:12 PM

Subject: Fw: URGENT ISSUE: 18405-1037 mouse study blood collection amendment -

---

Hi Rose...Jane is away on vacation, and out of communication range.

My personal, and DuPont company, apologies for this late and urgent 'non-objection' request consideration, but our GenX Toxicity Team has just realized that we overlooked a CRITICAL study design issue in the 18405-1937 Mouse Study Blood Collection Amendment just approved by EPA.

The details are outlined in the Notes from Randy Frame and Sue Munley, shown below.

Given the circumstances and timing, what options do we have to proceed, with EPA agreement, for what Randy and Sue recommend (i.e. a non-objection to proceed).

We fully realize this may be difficult to impossible, but I wanted to make fully sure that what ever we do is totally right.

Many thx for your advice...best regards, Jim

Jim Hoover, FPS Global Regulatory Manager

DuPONT DCF/FPS
CRP 702, Room 2116

Wilmington, DE 19880

BBerry: Personal Phone / Ex. 6

----- Forwarded by James R Hoover/AE/DuPont on 04/30/2010 02:50 PM -----
Steven R Frame/AE/DuPont

To James R Hoover/AE/DuPont@DuPont, Jane Bradd Andersen/AE/DuPont@DuPont

04/30/2010 11:46 AM

cc Gary W Jepson/AE/DuPont@DuPont, Susan M Munley/AE/DuPont@DuPont

Subject URGENT ISSUE: 18405-1037 mouse study blood collection amendment -

Jim, Jane,

Please see Sue's note below. In order to get any useful results from the blood collection on adult females in the mouse study, we need to administer a dose on the day of sacrifice (in the current protocol, the last dose is the day before sacrifice). Without a day-of-sacrifice dosing, the blood data from the moms will be of little value. Therefore, it is near certain the EPA would concur with this minor change in procedure since they suggested the blood collection in the first place, and they undoubtedly want the most useful information. Further, this would have no effect on the study results since the animals are sacrificed very soon after the extra dose. Nevertheless, we will need your OK, and EPA's OK to proceed, and we must have this OK before Monday due to the stage of the test we are in. The new amendment could be to the EPA on Monday or soon thereafter.

Randy

----- Forwarded by Steven R Frame/AE/DuPont on 04/30/2010 11:38 AM -----
Susan M Munley/AE/DuPont

To Steven R Frame/AE/DuPont@DuPont, Gary W Jepson/AE/DuPont@DuPont

04/30/2010 11:37 AM

cc

Subject 18405-1037 mouse study blood collection amendment - URGENT ISSUE

While preparing to execute the blood collection for plasma TK as dictated by the recently-approved protocol amendment 4, we realized that we overlooked a

CRITICAL study design issue.

As per protocol, adult animals are scheduled to be dosed through one day PRIOR to scheduled euthanasia.

Based on existing data, blood collection scheduled for two hours following the last dose is the optimal and most meaningful time for collection.

We cannot obtain enough volume for this work without making the bleed a terminal bleed.

Therefore, we need to write another amendment (draft attached below) to specify that animals will be administered a single additional dose on the morning of scheduled euthanasia and then euthanized two hours following that dose.

I am writing to seek non-objection to proceed with this beginning this coming Monday morning, May 3.

The first F0 females to reach PND 21 are scheduled to have their litters weaned and be subsequently euthanized this coming Monday morning.

As these procedures will clarify and improve upon the data dictated by the previously approved amendment 4, please let me know if we can proceed with approving this work to begin on Monday.

189225 Draft Amendment 5 043010.doc 189225 Draft Amendment 5 043010.doc

Submit Time: 7/26/2018 15:49:00
From: CN=Laurence Libelo/OU=DC/O=USEPA/C=US
To: CN=Laurence Libelo/OU=DC/O=USEPA/C=US@MSO365
Cc:
Subject: Fw: From Ohio/West Virginia -- New DuPont/WVDEP Consent Order for New PFCs

----- Forwarded by Laurence Libelo/DC/USEPA/US on 07/26/2018 11:48 AM -----

From: Laurence Libelo/DC/USEPA/US
To: Laurence Libelo/DC/USEPA/US@MSO365,
Date: 07/26/2018 11:40 AM
Subject: Fw: From Ohio/West Virginia -- New DuPont/WVDEP Consent Order for New PFCs

---

----- Forwarded by Laurence Libelo/DC/USEPA/US on 07/26/2018 11:39 AM -----

From: Mark Strynar/RTP/USEPA/US
To: Laurence Libelo/DC/USEPA/US@EPA,
Cc: Andrew Lindstrom/RTP/USEPA/US@EPA
Date: 11/29/2011 02:30 PM
Subject: Re: Fw: From Ohio/West Virginia -- New DuPont/WVDEP Consent Order for New PFCs

---

Laurence,

I misspoke. I actually do see more of the CAS# 13252-13-6 structure you sent. It was the dissociated ion. What I was calling the DuPont product (structure below with 2 CF3 groups between ether and carboxylic acid) was over 10X lower in concentration. Interestingly I see a mass of +4 CF2 groups that is a little more than half the response of this target compound.However I am not sure where the extra CF2 s are right now.

Mark

Dr. Mark J. Strynar
USEPA ORD/NERL
Physical Scientist
phone 919-541-3706
fax 919-541-3527

Laurence Libelo---11/29/2011 12:58:59 PM---Could be an impurity? Did you see the CAS # 62037-80-3 NH4 salt or the disassociated ion?

From: Laurence Libelo/DC/USEPA/US
To: Mark Strynar/RTP/USEPA/US@EPA
Date: 11/29/2011 12:58 PM
Subject: Re: Fw: From Ohio/West Virginia -- New DuPont/WVDEP Consent Order for New PFCs

---

Could be an impurity?

Did you see the CAS # 62037-80-3 NH4 salt or the disassociated ion?

Mark Strynar---11/29/2011 11:40:17 AM---Laurence, That is not what we looked for and seemed to find in Fayetteville. This is the structure

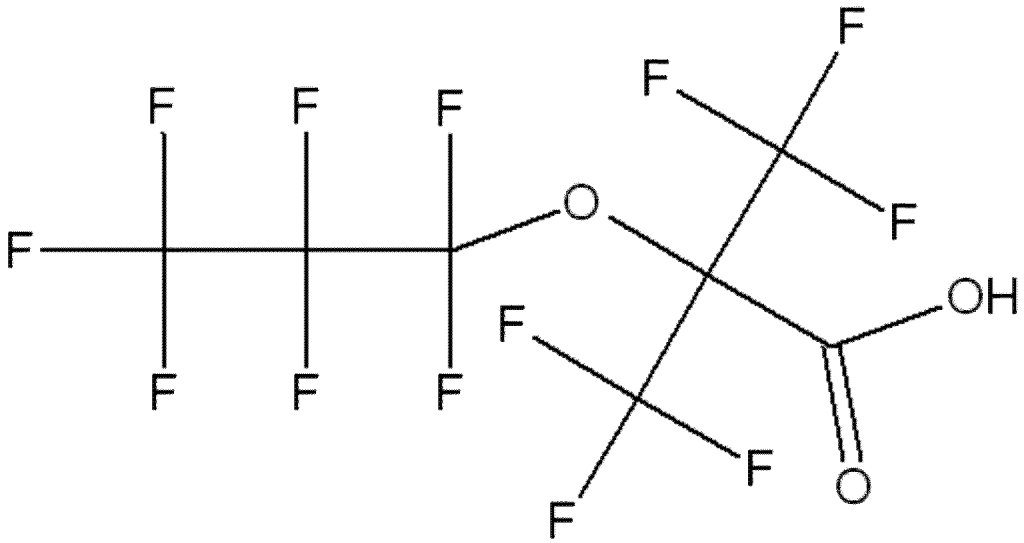
From: Mark Strynar/RTP/USEPA/US
To: Laurence Libelo/DC/USEPA/US@EPA
Cc: Andrew Lindstrom/RTP/USEPA/US@EPA, John Washington/ATH/USEPA/US@EPA
Date: 11/29/2011 11:40 AM
Subject: Re: Fw: From Ohio/West Virginia -- New DuPont/WVDEP Consent Order for New PFCs

---

Laurence,

That is not what we looked for and seemed to find in Fayetteville. This is the structure I think we found (and a homologous series).

Mark



Dr. Mark J. Strynar
USEPA ORD/NERL
Physical Scientist
phone 919-541-3706
fax 919-541-3527

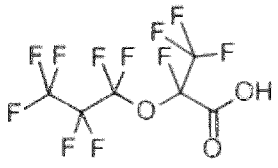
Laurence Libelo---11/29/2011 11:03:39 AM---Here is some info on DuPont's replacement for PFOA at Parkersburg. (CAS # 13252-13-6)

From: Laurence Libelo/DC/USEPA/US
To: Mark Strynar/RTP/USEPA/US@EPA, Andrew Lindstrom/RTP/USEPA/US@EPA, John Washington/ATH/USEPA/US@EPA
Date: 11/29/2011 11:03 AM
Subject: Fw: From Ohio/West Virginia -- New DuPont/WVDEP Consent Order for New PFCs

Here is some info on DuPont's replacement for PFOA at Parkersburg.

(CAS # 13252-13-6)

p « E http://www.chemicalbook.com/ProdSupplierGN_EN.aspx?CBNumber=CB8401458aspnetForm1



13252-13-6

[redacted]

----- Forwarded by Laurence Libelo/DC/USEPA/US on 11/29/2011 11:01 AM -----

From: Mark Garvey/DC/USEPA/US
To: David Lynch/DC/USEPA/US@EPA, Benjamin Bahk/DC/USEPA/US@EPA, Laurence Libelo/DC/USEPA/US@EPA
Date: 11/29/2011 10:12 AM
Subject: Fw: From Ohio/West Virginia -- New DuPont/WVDEP Consent Order for New PFCs

---

David, Laurence and Ben,

The Citizen's Suit attorney - Rob Billot involved in the PFOA TSCA 8(e) case in 2005, is sending a WV Order below.

Mark

Mark Garvey
Attorney
202-564-4168
US EPA
Office of Civil Enforcement
Garvey.Mark@epa.gov

NOTE: This email and its attachments may contain confidential information, attorney work product, enforcement sensitive material or privileged information. If you have received this transmission in error, please delete it.

----- Forwarded by Mark Garvey/DC/USEPA/US on 11/29/2011 10:09 AM -----

From: "Bilott, Robert A." <bilott@taftlaw.com>
To: Mark Garvey/DC/USEPA/US@EPA, Ilana Saltzbart/DC/USEPA/US@EPA
Date: 11/29/2011 10:04 AM
Subject: New DuPont/WVDEP Consent Order for New PFCs

FYI

Taft /

Robert A. Bilott / Partner
Taft Stettinius & Hollister LLP
425 Walnut Street, Suite 1800
Cincinnati, Ohio 45202-3957
Tel: 513.381.2838 • Fax: 513.381.0205
Direct: 513.357.9638 • Cell: Personal Phone / Ex. 6
www.taftlaw.com / bilott@taftlaw.com

###
-----Original Message-----
From: dep.online@wv.gov [mailto:dep.online@wv.gov]
Sent: Monday, November 28, 2011 10:10 AM
To: Bilott, Robert A.
Subject: DEP Public Notice - County - Wood - Applicant - E I DuPont De Nemours & Co - Application No. WV0001279

The following was sent to you because you are a
Member of the DEP Public Notice mailing list.
==========
Monday, November 28, 2011 @ 10:09 AM
==========

STATE OF WEST VIRGINIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
DIVISION OF WATER AND WASTE MANAGEMENT

PUBLIC NOTICE

WEST VIRGINIA DEPARTMENT OF ENVIRONMENTAL PROTECTION'S, PUBLIC INFORMATION OFFICE, 601 57TH STREET SE, CHARLESTON, WEST VIRGINIA 25304-2345 TELEPHONE: (304) 926-0440.

INTENT TO ENTER AN ADMINISTRATIVE CONSENT ORDER UNDER THE WEST VIRGINIA WATER POLLUTION CONTROL ACT

Public Notice No.: L-136-11 Public Notice
Date: November 26, 2011

Paper: Parkersburg News

The following has been agreed to by The WV Department of Environmental Protection (WVDEP) and E I DuPont Nemours & Co. to the terms and conditions of a Consent Order for this facility or activity:

Permit No.: WV0001279

Order No: 7418

Permittee: E I DUPONT DE NEMOURS & CO
PO BOX 1217
WASHINGTON, WV 26181

Location: WASHINGTON, WOOD COUNTY

Latitude: 39:16:19 Longitude: 81:39:42

Receiving Stream:
OHIO RIVER

Activity:

The WV Department of Environmental Protection (WVDEP) and E I DuPont Nemours & Co. have proposed an Administrative Consent Order that will allow DuPont to begin construction activities in connection with necessary upgrades to the waste water treatment system and to commence commercial scale production using their new patented technology for a new processing aid for the production of high-performance fluoropolymers using a new compound.

Business conducted:

Production of polymer resins; compounded plastics; nylon fibers; formaldehyde;

fluorocarbon polymers, monomers, telomers; and calcium fluoride.

Implementation:
Compliance shall be attained through the issuance of Order No. 7418, and any revisions, thereto.

On the basis of review of the materials, the "Water Pollution Control Act (Chapter 22, Article 11-8(a))," and the "West Virginia Legislative Rules," the State of West Virginia will act on the above action.

Any interested person may submit written comments on the draft Order and may request a public hearing by addressing such to the Director of the Division of Water and Waste Management within 30 days of the date of the public notice. Such comments or requests should be addressed to:
Director, Division of Water and Waste Management, DEP
ATTN: Lori Devereux, Permitting Section
601 57th Street SE
Charleston, WV 25304-2345

The public comment period begins November 26, 2011 ends December 26, 2011.

Comments received within this period will be considered prior to acting on the Order. Correspondence should include the name, address and the telephone number of the writer and a concise statement of the nature of the issues rose. The Director shall hold a public hearing whenever a finding is made, on the basis of requests, that there is a significant degree of public interest on issues relevant to the draft Order(s). Interested persons may contact the public information office to obtain further information.

The draft Order and any pertinent data may be inspected, by appointment, at the Division of Water and Waste Management Public Information Office, at 601 57th Street SE, Charleston, WV 25304-2345, between 8:00 a.m. and 4:00 p.m. on business days. Copies of the documents may be obtained from the Division at a nominal cost. Individuals requiring Telecommunication Device (TDD) may contact our agency by calling (304) 926-0493. Calls must be made 8:30 a.m. to 4:30 p.m. Monday through Friday.

==========
To view past notices of open public comment periods or to unsubscribe from this Mailing List, login at:
http://apps.dep.wv.gov//MLists2/

[attachment "DuPont Final Version.pdf" deleted by Mark Strynar/RTP/USEPA/US]

SPILMAN THOMAS & BATTLE, PLLC
ATTORNEYS AT LAW

Direct Dial: 304-340-3832
kcrockett@spilmanlaw.com

November 21, 2011

VIA HAND DELIVERY

Mr. Yogesh Patel
West Virginia Department of Environmental Protection
601 57th Street, S.E.
Charleston, WV 25304

Re: Executed Draft Consent Order No. 7418

Dear Yogesh,

Please find enclosed for your records the original copy of the above-referenced draft Consent Order, as executed on behalf of E. I. du Pont de Nemours and Company on November 18, 2011.

Should you have any questions, please do not hesitate to call me at (304) 340-3832. Thank you for your continued attention to this matter.

Very truly yours,

M. Katherine Crockett

M. Katherine Crockett

MKC:ksw

Enclosure

west virginia department of environmental protection

Division of Water and Waste Management
601 57th Street SE
Charleston, WV 25304-2345
Telephone Number: (304) 926-0495
Fax Number: (304) 926-0463

Earl Ray Tomblin, Governor
Randy C. Huffman, Cabinet Secretary
www.dep.wv.gov

CONSENT ORDER
ISSUED UNDER THE
WATER POLLUTION CONTROL ACT
WEST VIRGINIA CODE, CHAPTER 22, ARTICLE 11

TO: E. I. du Pont de Nemours and Company
Washington Works
c/o Karl J. Boelter, Plant Manager
P. O. Box 1217
Washington, WV 26181-1217

DATE: ~~11/18/2011~~

ORDER NO.: 7418

INTRODUCTION

This Consent Order is issued by the Director of the Division of Water and Waste Management, Department of Environmental Protection, (hereinafter, the "Director") under the authority of Chapter 22, Article 11, Section 1, *et. seq.* of the Code of West Virginia to E. I. du Pont de Nemours and Company (hereinafter "DuPont").

FINDINGS OF FACT

In support of this Order, the Director hereby finds the following:

1. DuPont operates a multiple product line manufacturing facility and associated industrial wastewater treatment plant located in Washington, Wood County, West Virginia. This facility is known as the Washington Works Plant ("Facility" or the "Plant").

2. This Facility is permitted under WV/NPDES Permit No. WV0001279 (the "Permit"), issued August 4, 2003 to authorize the Plant's point source discharges into the Ohio River or tributaries thereof.

3. In accordance with 47 CSR 10-4.3, DuPont timely applied for renewal of the Permit on December 20, 2007, over 180 days prior to the Permit's scheduled expiration date of June 30, 2008.

4. Since DuPont's submittal of its renewal application, WVDEP has administratively extended the Permit. As of the date of this Consent Order, the Permit remains administratively extended until December 31, 2011.

5. DuPont has developed patented technology for a new-generation processing aid for the production of high-performance fluoropolymers using a new compound C3 Dimer Acid/Salt (CAS # 13252-13-6 and CAS # 62037-80-3) (hereafter the "New Compound"). DuPont represents that this technology is a sustainable solution that includes a new processing aid with a favorable toxicological profile and rapid bioelimination. DuPont further represents that it will utilize environmental control technologies that reduce environmental release and exposure. The U.S. EPA, through a Toxic Substances Control Act Section 5(e) Consent Order ("TSCA Order") executed by DuPont on January 28, 2009, granted DuPont approval, under conditions set forth in the TSCA Order, to commercially manufacture, process, and distributes the processing aid. The TSCA Order requires that DuPont shall recover and capture (destroy) or recycle the New Compound "at an overall efficiency of 99% from all the effluent streams and the air emissions (point source and fugitive)." This requirement is interpreted by DuPont to be applied in the aggregate on an annual basis, for all U.S. sites where the New Compound is used. The wastewater treatment system for the Facility's fluoropolymers processes will be modified to achieve the TSCA Order requirements at present and future production capacity.

6. At this time, based on the results of its ongoing research and development activities, DuPont is planning to undertake construction of related upgrades to the Facility's wastewater treatment system for fluoropolymers processes currently discharging through internal Outlets 102 and 305, in conjunction with the use of the New Compound, and to commence the initial phase of commercial-scale production using the New Compound.

7. The planned upgrades to the fluoropolymers wastewater treatment system include new higher efficiency processing aid recovery, addition of a new reverse osmosis ("RO") system, and expansion of the existing carbon bed systems.

8. The Director cannot modify a WV/NPDES permit that has been administratively extended beyond its original expiration date. Accordingly, WVDEP cannot currently modify the Permit to authorize DuPont to scale up the use of the New Compound, to discharge the New Compound, and to undertake the related wastewater treatment plant upgrades described in Paragraphs 6-7, above.

9. DuPont provided toxicity data to WVDEP in March of 2011. Since that time, ongoing dialogue has occurred and additional information shared between the parties regarding the planned upgrades and the New Compound. On August 3, 2011, DuPont provided additional toxicological information as well as plans to begin production using the New Compound to the WVDEP.

10. The parties have entered into this Consent Order as the most expedient mechanism to allow DuPont to begin construction activities in connection with necessary upgrades to the wastewater treatment system and to commence commercial scale production using

the New Compound, as described in Paragraphs 5 and 6 above, pending the Director's renewal of the Permit. This Consent Order does not constitute and shall not be construed as a finding by the Director that DuPont has committed any violation(s) of the terms and conditions of the Permit.

ORDER FOR COMPLIANCE

Now, therefore, in accordance with Chapter 22, Article 11, Section 1 *et seq.* of the West Virginia Code, it is hereby ORDERED by the Director as follows:

1. DuPont shall undertake construction activities associated with the above-described wastewater treatment plant upgrades in accordance with the following schedule:

    a. Modifications to the Granular Mother Liquor ("GML")/Lamella system to achieve enhanced solids removal shall be initiated no later than six months after the effective date of this Consent Order.
    b. Construction of a new stage 1 RO unit with new membrane technology for enhanced processing aid recovery shall be initiated no later than 12 months after the effective date of this Consent Order.
    c. Sub-micron filtration and additional RO units for recovery of processing aid from previously non-recoverable process streams, and carbon beds for capture of processing aid shall be installed no later than 24 months after the effective date of this Consent Order.
    d. Additional carbon beds in W9 Line 1 for enhanced abatement capability when carbon change-outs occur shall be installed no later than 24 months after the effective date of this Consent Order.
    e. Connection of production areas to new recovery/abatement system as reflected in the permit application shall occur no later than 24 months after the effective date of this Consent Order.

2. During the period of transition to the new processing aid and treatment system upgrades, wastewaters from fluoropolymers processes covered by these changes shall continue to be treated by existing treatment facilities such that all wastestreams that are currently receiving treatment via activated carbon will continue to receive such treatment. DuPont has indicated that the New Compound will require more frequent change-outs of carbon in the carbon beds in order to maintain treatment removal efficiencies. DuPont shall replace the lead bed of granulated activated carbon within seven (7) days of detecting break-through of the New Compound from the lead bed while maintaining an effective polish bed in the system or cease discharge from the affected carbon bed system. Should monitoring detect break-through from the final polish bed, DuPont shall cease discharge from the affected carbon bed system within 24 hours of detecting such break-through until unspent carbon is in place to treat that wastestream. For purposes of this Consent Order, "break-through" will be deemed to have occurred when concentrations of the New Compound are detected at 1 mg/l or greater using the analytical method specified in Paragraph 5, below. This requirement shall apply to internal Outlets 102, 305 and a new internal monitoring location being designated as internal Outlet 605. Further, DuPont

shall operate and maintain the granulated activated carbon beds at internal Outlets 102, 305 and 605 in a manner to prevent the inhibition of treatment of other pollutants.

3. Based on the toxicological information provided and all other information available at this time, WVDEP has determined that a concentration of no more than 17.5 ug/l of the New Compound in the receiving stream outside of an applicable mixing zone will be protective of West Virginia's narrative water quality standards found in 47 CSR 2, Section 3 of the West Virginia Legislative Rules. To this end, WVDEP has established the discharge limitations for the New Compound as set out in Paragraph 4, below.

4. DuPont shall adhere to the following limitations and perform the following self-monitoring for the New Compound during the term of this Order in accordance with the following:

Outlet	Monthly Average	Maximum Daily	Units	Monitoring Frequency	Sample Type
102[A]	Monitor	Monitor	ug/l	1/day[D]	Grab
102[B]	Monitor	Monitor	ug/l	1/week[D]	Grab
305[A]	Monitor	Monitor	ug/l	1/day[D]	Grab
305[B]	Monitor	Monitor	ug/l	1/week[D]	Grab
605[A,C]	Monitor	Monitor	ug/l	1/day[D]	Grab
605[B,C]	Monitor	Monitor	ug/l	1/week[D]	Grab
002	77[E]	112[E]	ug/l	1/week	24-hour Composite
005	191[E]	278[E]	ug/l	1/week	24-hour Composite

[A] Monitoring location after exiting lead activated carbon bed and prior to entering polish activated carbon bed.
[B] Monitoring location after exiting the polish activated carbon bed.
[C] Discharge from carbon treatment system located in building 127.
[D] When discharging.
[E] As discussed in Paragraph 3, above, these limits have been calculated to ensure a concentration of no more than 17.5 ug/l in the receiving stream outside of the applicable mixing zone, as determined by application of the mixing zone dilution factor for the respective outlet specified in the current Fact Sheet for the Permit.

5. Samples taken at Outlets 002 and 005 pursuant to Paragraph 4 above shall be analyzed by Liquid Chromatography/Mass Spectrometry/Mass Spectrometry ("LC/MS/MS") with a method detection limit ("MDL") of 1 ug/l or less. Samples taken at internal Outlets 102, 305 and 605 pursuant to Paragraph 4 above shall be analyzed by Liquid Chromatography ("LC") or Gas Chromatography ("GC") per internal plant method with an MDL of 1 mg/l or less.

6. Outlet results for sampling performed pursuant to Paragraph 4 above shall be reported monthly to the WVDEP on the attached Discharge Monitoring Reports ("DMRs"). In addition, DuPont shall maintain a log of the results of the daily monitoring required by Paragraph 4 at internal Outlets 102, 305 and 605, and shall submit this log to WVDEP on a monthly basis as an attachment to its DMR.

7. Commercial production using the New Compound and generating wastewaters for on-site treatment may commence upon the execution of this Order, subject to compliance with the provisions of this Order.

8. This Consent Order may be reopened and revised by agreement of the parties to prescribe additional and/or different requirements, including different monitoring requirements and/or increased or decreased discharge limitations, pursuant to any new information or data regarding the New Compound.

9. This Order shall terminate upon notification by DuPont that the actions required by the Order of Compliance have been completed and the Director's written concurrence therewith or upon the issuance by WVDEP of a renewed permit for the Facility that authorizes the activities covered by this Order that have not been completed as of that time, whichever occurs earlier.

OTHER PROVISIONS

1. DuPont hereby waives its right to appeal this Order under the provisions of Chapter 22, Article 11, Section 21 of the Code of West Virginia. Under this Order, DuPont agrees to take all actions required by the terms and conditions of this Order and consents to and will not contest the Director's jurisdiction regarding this Order. However, DuPont does not admit to any factual and legal determinations made by the Director and reserves all rights and defenses available regarding liability or responsibility in any proceedings regarding DuPont other than proceedings, administrative or civil, to enforce this Order.

2. If any event occurs which causes delay in the achievement of the requirements of this Order, DuPont shall have the burden of proving that the delay was caused by circumstances beyond its reasonable control which could not have been overcome by due diligence (i.e., force majeure). Force majeure shall not include delays caused or contributed to by the lack of sufficient funding. Within three (3) working days after DuPont becomes aware of such a delay, DuPont shall provide written notification to the Director. Within ten (10) working days of initial notification, DuPont shall submit a detailed written explanation of the anticipated length and cause of the delay, the measures taken and/or to be taken to prevent or minimize the delay, and a timetable by which DuPont intends to implement these measures. If the Director agrees that the delay has been or will be caused by circumstances beyond the reasonable control of DuPont (i.e., force majeure), the time for performance hereunder shall be extended for a period of time equal to the delay resulting from such circumstances. A force majeure amendment

granted by the Director shall be considered a binding extension of this Order and of the requirements herein. The determination of the Director shall be final and not subject to appeal.

3. Compliance with the terms and conditions of this Order shall not in any way be construed as relieving DuPont of the obligation to comply with any applicable law, permit, other order, or any other requirement otherwise applicable. Violations of the terms and conditions of this Order may subject DuPont to additional penalties and injunctive relief in accordance with the applicable law.

4. The provisions of this Order are severable and should a court or board of competent jurisdiction declare any provisions to be invalid or unenforceable, all other provisions shall remain in full force and effect.

5. This Order is binding on DuPont, its successors and assigns.

This Order shall become effective upon the date on which a true and correct copy of this fully executed Order is received by DuPont.

Karl J. Boelter, Plant Manager
Washington Works
E. I. du Pont de Nemours and Company

11/18/11
Date

Public Notice begin: _____
Date

Public Notice end: _____
Date

Scott G. Mandirola, Director
Division of Water and Waste Management
West Virginia Department of Environmental Protection

Date

SGM:rt/mls

Enclosure(s)
cc: Environmental Inspector
Environmental Inspector Supervisor
EPA Region III

Submit Time: 2/7/2012 18:29:31
From: CN=Laurence Libelo/OU=DC/O=USEPA/C=US
To: CN=Andrew Lindstrom/OU=RTP/O=USEPA/C=US@EPA CN=Mark Strynar/OU=RTP/O=USEPA/C=US@EPA
Cc:
Subject: Fw: DuPont PFOA Replacement Permit

FYI
----- Forwarded by Laurence Libelo/DC/USEPA/US on 02/07/2012 01:29 PM -----

From: Cathy Fehrenbacher/DC/USEPA/US
To: Laurence Libelo/DC/USEPA/US@EPA
Date: 02/07/2012 11:48 AM
Subject: Fw: DuPont PFOA Replacement Permit

Cathy Fehrenbacher, CIH, Chief
Exposure Assessment Branch
USEPA/Office of Pollution Prevention and Toxics
1200 Pennsylvania Ave., N.W. (7406M)
Washington, DC 20460
Phone: 202-564-8551
Fax: 202-564-8892

Deliveries:
Room 5102A EPA East Building
1201 Constitution Avenue, N.W.
Washington, DC 20004
----- Forwarded by Cathy Fehrenbacher/DC/USEPA/US on 02/07/2012 11:47 AM -----

From: "Bilott, Robert A." <bilott@taftlaw.com>
To: Cathy Fehrenbacher/DC/USEPA/US@EPA, KarenD Johnson/R3/USEPA/US@EPA, Toni Krasnic/DC/USEPA/US@EPA
Date: 02/07/2012 10:24 AM
Subject: DuPont PFOA Replacement Permit

FYI

Taft /

Robert A. Bilott / Partner
Taft Stettinius & Hollister LLP
425 Walnut Street, Suite 1800
Cincinnati, Ohio 45202-3957
Tel: 513.381.2838 • Fax: 513.381.0205
Direct: 513.357.9638 • Cell: Personal Phone / Ex. 6
www.taftlaw.com / bilott@taftlaw.com

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[Untitled].pdf  [Untitled].pdf

Submit Time: 11/29/2011 17:40:49
From: CN=Laurence Libelo/OU=DC/O=USEPA/C=US
To: CN=Andrew Lindstrom/OU=RTP/O=USEPA/C=US@EPA
Cc:
Subject: Re: Fw: From Ohio/West Virginia -- New DuPont/WVDEP Consent Order for New PFCs

Good questions. Let's chat.

Andrew Lindstrom---11/29/2011 11:48:24 AM---Laurence, Does anyone have any idea how stable the ether bond is under different conditions? In viv

> From: Andrew Lindstrom/RTP/USEPA/US
> To: Laurence Libelo/DC/USEPA/US@EPA
> Date: 11/29/2011 11:48 AM
> Subject: Re: Fw: From Ohio/West Virginia -- New DuPont/WVDEP Consent Order for New PFCs

---

Laurence,

Does anyone have any idea how stable the ether bond is under different conditions? In vivo? In a river?

Thank you,

Andy

Laurence Libelo---11/29/2011 11:03:49 AM---Here is some info on DuPont's replacement for PFOA at Parkersburg. (CAS # 13252-13-6)

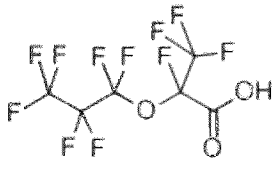
> From: Laurence Libelo/DC/USEPA/US
> To: Mark Strynar/RTP/USEPA/US@EPA, Andrew Lindstrom/RTP/USEPA/US@EPA, John Washington/ATH/USEPA/US@EPA
> Date: 11/29/2011 11:03 AM
> Subject: Fw: From Ohio/West Virginia -- New DuPont/WVDEP Consent Order for New PFCs

---

Here is some info on DuPont's replacement for PFOA at Parkersburg.

(CAS # 13252-13-6)

p « E http://www.chemicalbook.com/ProdSupplierGN_EN.aspx?CBNumber=CB8401458aspnetForm1



13252-13-6

[redacted]

----- Forwarded by Laurence Libelo/DC/USEPA/US on 11/29/2011 11:01 AM -----

From: Mark Garvey/DC/USEPA/US
To: David Lynch/DC/USEPA/US@EPA, Benjamin Bahk/DC/USEPA/US@EPA, Laurence Libelo/DC/USEPA/US@EPA
Date: 11/29/2011 10:12 AM
Subject: Fw: From Ohio/West Virginia -- New DuPont/WVDEP Consent Order for New PFCs

---

David, Laurence and Ben,

The Citizen's Suit attorney - Rob Billot involved in the PFOA TSCA 8(e) case in 2005, is sending a WV Order below.

Mark

Mark Garvey
Attorney
202-564-4168
US EPA
Office of Civil Enforcement
Garvey.Mark@epa.gov

----- Forwarded by Mark Garvey/DC/USEPA/US on 11/29/2011 10:09 AM -----

From: "Bilott, Robert A." <bilott@taftlaw.com>
To: Mark Garvey/DC/USEPA/US@EPA, Ilana Saltzbart/DC/USEPA/US@EPA
Date: 11/29/2011 10:04 AM
Subject: New DuPont/WVDEP Consent Order for New PFCs

FYI

Taft /

Robert A. Bilott / Partner
Taft Stettinius & Hollister LLP
425 Walnut Street, Suite 1800
Cincinnati, Ohio 45202-3957
Tel: 513.381.2838 • Fax: 513.381.0205
Direct: 513.357.9638 • Cell: Personal Phone / Ex. 6
www.taftlaw.com / bilott@taftlaw.com

###
-----Original Message-----
From: dep.online@wv.gov [mailto:dep.online@wv.gov]
Sent: Monday, November 28, 2011 10:10 AM
To: Bilott, Robert A.
Subject: DEP Public Notice - County - Wood - Applicant - E I DuPont De Nemours & Co - Application No. WV0001279

The following was sent to you because you are a
Member of the DEP Public Notice mailing list.
==========
Monday, November 28, 2011 @ 10:09 AM
==========

STATE OF WEST VIRGINIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
DIVISION OF WATER AND WASTE MANAGEMENT

PUBLIC NOTICE

WEST VIRGINIA DEPARTMENT OF ENVIRONMENTAL PROTECTION'S, PUBLIC INFORMATION OFFICE, 601 57TH STREET SE, CHARLESTON, WEST VIRGINIA 25304-2345 TELEPHONE: (304) 926-0440.

INTENT TO ENTER AN ADMINISTRATIVE CONSENT ORDER UNDER THE WEST VIRGINIA WATER POLLUTION CONTROL ACT

Public Notice No.: L-136-11 Public Notice
Date: November 26, 2011

Paper: Parkersburg News

The following has been agreed to by The WV Department of Environmental Protection (WVDEP) and E I DuPont Nemours & Co. to the terms and conditions of a Consent Order for this facility or activity:

Permit No.: WV0001279

Order No: 7418

Permittee: E I DUPONT DE NEMOURS & CO
PO BOX 1217
WASHINGTON, WV 26181

Location: WASHINGTON, WOOD COUNTY

Latitude: 39:16:19 Longitude: 81:39:42

Receiving Stream:
OHIO RIVER

Activity:

The WV Department of Environmental Protection (WVDEP) and E I DuPont Nemours & Co. have proposed an Administrative Consent Order that will allow DuPont to begin construction activities in connection with necessary upgrades to the waste water treatment system and to commence commercial scale production using their new patented technology for a new processing aid for the production of high-performance fluoropolymers using a new compound.

Business conducted:

Production of polymer resins; compounded plastics; nylon fibers; formaldehyde; fluorocarbon polymers, monomers, telomers; and calcium fluoride.

Implementation:
Compliance shall be attained through the issuance of Order No. 7418, and any revisions, thereto.

On the basis of review of the materials, the "Water Pollution Control Act (Chapter 22, Article 11-8(a))," and the "West Virginia Legislative Rules," the State of West Virginia will act on the above action.

Any interested person may submit written comments on the draft Order and may request a public hearing by addressing such to the Director of the Division of Water and Waste Management within 30 days of the date of the public notice. Such comments or requests should be addressed to:
Director, Division of Water and Waste Management, DEP
ATTN: Lori Devereux, Permitting Section
601 57th Street SE
Charleston, WV 25304-2345

The public comment period begins November 26, 2011 ends December 26, 2011.

Comments received within this period will be considered prior to acting on the Order. Correspondence should include the name, address and the telephone number of the writer and a concise statement of the nature of the issues rose. The Director shall hold a public hearing whenever a finding is made, on the basis of requests, that there is a significant degree of public interest on issues relevant to the draft Order(s). Interested persons may contact the public information office to obtain further information.

The draft Order and any pertinent data may be inspected, by appointment, at the Division of Water and Waste Management Public Information Office, at 601 57th Street SE, Charleston, WV 25304-2345, between 8:00 a.m. and 4:00 p.m. on business days. Copies of the documents may be obtained from the Division at a nominal cost. Individuals requiring Telecommunication Device (TDD) may contact our agency by calling (304) 926-0493. Calls must be made 8:30 a.m. to 4:30 p.m. Monday through Friday.

==========

To view past notices of open public comment periods or to unsubscribe from this Mailing List, login at: http://apps.dep.wv.gov//MLists2/

[attachment "DuPont Final Version.pdf" deleted by Andrew Lindstrom/RTP/USEPA/US]

Subject: Re: Fw: URGENT ISSUE: 18405-1037 mouse study blood collection amendment -
From: CN=Greg Schweer/OU=DC/O=USEPA/C=US
To: CN=Jennifer Seed/OU=DC/O=USEPA/C=US@EPA
Cc:
Submit Time: 5/3/2010 14:32:21

Thanks Jennifer. I was out of the office on Friday and did not learn about Jim's reequest until 4pm. Were not many folks available at that time on a Friday.

Greg Schweer
Chief, New Chemicals Management Branch
Chemical Control Division
U.S. EPA, Office of Pollution Prevention and Toxics
(202)564-8469

-----Jennifer Seed/DC/USEPA/US wrote: -----

To: James R Hoover <James.R.Hoover@USA.dupont.com>
From: Jennifer Seed/DC/USEPA/US
Date: 05/03/2010 09:03AM
cc: Greg Schweer/DC/USEPA/US@EPA
Subject: Re: Fw: URGENT ISSUE: 18405-1037 mouse study blood collection amendment -

Jim,

Sorry about the confusion over this. The protocol is fine. I hope you get this message in time.

Jennifer

Jennifer Seed, PhD
Deputy Director
Risk Assessment Division, OPPT
202-564-7634
seed.jennifer@epa.gov

James R Hoover ---04/30/2010 04:16:12 PM---Jennifer....Greg Schweer directed me to Jim Allwood, and Jim told me to foward this EMail and give

Fr James R Hoover <James.R.Hoover@USA.dupont.com>
om
:

To: Jennifer Seed/DC/USEPA/US@EPA

Da 04/30/2010 04:16 PM
te:

Su Fw: URGENT ISSUE: 18405-1037 mouse study blood collection amendment -
bje
ct:

Jennifer....Greg Schweer directed me to Jim Allwood, and Jim told me to foward this EMail and give you a quick call, so I will call in a minute. May apologies for this,best rgds, Jim

----- Forwarded by James R Hoover/AE/DuPont on 04/30/2010 04:14 PM -----

James R Hoover/AE/DuPont

04/30/2010 03:57 PM

To schweer.greg@epa.gov

cc

Subject Fw: URGENT ISSUE: 18405-1037 mouse study blood collection amendment -

Hi Greg....My personal apologies for this very late discovery, and even later communication to Rose and to you, on this issue. This is clearly our mistake, and I take full responsibility for it.

I called Rose to give her a heads-up on the enclosed EMails (below). I now understand from Rose's Voicemail that she is out today.

For us to proceed as indicated, I think we would need a "non-objection" Email from EPA relative to this EMail before 6:00am this coming Monday morning (May 3rd).

The details are show below.

Any advice would be much appreciated. We fully realize this may be difficult to impossible, but I wanted to make fully sure that what ever we do is totally right.

Again, my apologies.

Very best regards, Jim

Jim Hoover, FPS Global Regulatory Manager

DuPONT DCF/FPS
CRP 702, Room 2116
Wilmington, DE 19880

BBerry Personal Phone / Ex. 6

----- Forwarded by James R Hoover/AE/DuPont on 04/30/2010 03:40 PM -----

James R Hoover/AE/DuPont

To Allison.Rose@epamail.epa.gov

cc Gary W Jepson/AE/DuPont@DuPont, Steven R Frame/AE/DuPont@DuPont, Susan M Munley/AE/DuPont@DuPont, Jane Bradd Andersen/AE/DuPont@DuPont

04/30/2010 03:11 PM

Subject: Fw: URGENT ISSUE: 18405-1037 mouse study blood collection amendment -

Hi Rose...Jane is away on vacation, and out of communication range.

My personal, and DuPont company, apologies for this late and urgent 'non-objection' request consideration, but our GenX Toxicity Team has just realized that we overlooked a CRITICAL study design issue in the 18405-1937 Mouse Study Blood Collection Amendment just approved by EPA.

The details are outlined in the Notes from Randy Frame and Sue Munley, shown below.

Given the circumstances and timing, what options do we have to proceed, with EPA agreement, for what Randy and Sue recommend (i.e. a non-objection to proceed).

We fully realize this may be difficult to impossible, but I wanted to make fully sure that what ever we do is totally right.

Many thx for your advice...best regards, Jim

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----- Forwarded by James R Hoover/AE/DuPont on 04/30/2010 02:50 PM -----

Steven R Frame/AE/DuPont

04/30/2010 11:46 AM

To James R Hoover/AE/DuPont@DuPont, Jane Bradd Andersen/AE/DuPont@DuPont

cc Gary W Jepson/AE/DuPont@DuPont, Susan M Munley/AE/DuPont@DuPont

Subject: URGENT ISSUE: 18405-1037 mouse study blood collection amendment -

Jim, Jane,

Please see Sue's note below. In order to get any useful results from the blood collection on adult females in the mouse study, we need to administer a dose on the day of sacrifice (in the current protocol, the last dose is the day before sacrifice). Without a day-of-sacrifice dosing, the blood data from the moms will be of little value. Therefore, it is near certain the EPA would concur with this minor change in procedure since they suggested the blood collection in the first place, and they undoubtedly want the most useful information. Further, this would have no effect on the study results since the animals are sacrificed very soon after the extra dose. Nevertheless, we will need your OK, and EPA's OK to proceed, and we must have this OK before Monday due to the stage of the test we are in. The new amendment could be to the EPA on Monday or soon thereafter.

Randy

----- Forwarded by Steven R Frame/AE/DuPont on 04/30/2010 11:38 AM -----

Susan M Munley/AE/DuPont

04/30/2010 11:37 AM

To Steven R Frame/AE/DuPont@DuPont, Gary W Jepson/AE/DuPont@DuPont

cc

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As per protocol, adult animals are scheduled to be dosed through one day PRIOR to scheduled euthanasia.

Based on existing data, blood collection scheduled for two hours following the last dose is the optimal and most meaningful time for collection.

We cannot obtain enough volume for this work without making the bleed a terminal bleed.

Therefore, we need to write another amendment (draft attached below) to specify that animals will be administered a single additional dose on the morning of scheduled euthanasia and then euthanized two hours following that dose.

I am writing to seek non-objection to proceed with this beginning this coming Monday morning, May 3.

The first F0 females to reach PND 21 are scheduled to have their litters weaned and be subsequently euthanized this coming Monday morning.

As these procedures will clarify and improve upon the data dictated by the previously approved amendment 4, please let me know if we can proceed with approving this work to begin on Monday.

*(See attached file: 189225 Draft Amendment 5 043010.doc)*189225 Draft Amendment 5 043010.doc

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To: James R Hoover <James.R.Hoover@USA.dupont.com>
Cc: CN=Greg Schweer/OU=DC/O=USEPA/C=US@EPA
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Submit Time: 5/3/2010 13:03:45

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Date: 04/30/2010 04:16 PM

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BBerry: **Personal Phone / Ex. 6**

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use of sender's contact information for direct marketing purposes or for transfers of data to third parties.

Francais Deutsch Italiano Espanol Portugues Japanese Chinese Korean

http://www.DuPont.com/corp/email_disclaimer.html

189225 Draft Amendment 5 043010.doc 189225 Draft Amendment 5 043010.doc

Nonconfidential List of TSCA Section 5(e) New Chemical Exposure Limits (NCELs)

Non-Confidential List of NCELs (end of 2011)

PMN Case #	Chemical Identity	NCEL (8-hour TWA)
P-84-0105	(G) Halogenated alkene	104 (mg/m^3)
P-84-0106	(G) Halogenated alkanes	14.5 (mg/m^3)
P-84-0107	(G) Halogenated alkanes	156 (mg/m^3)
P-84-0660	Benzene, ethenyl-, ar-bromo derivs. [CAS# 125904-11-2]	0.3 (ppm)
P-84-0704	Benzene, (2-bromoethyl)-, ar-bromo derivs. [CAS# 125904-10-1]	0.3 (ppm)
P-85-0433	1-Propanol, 3-mercapto- [CAS# 19721-22-3]	0.5 (ppm)
P-87-1881	1,4-Cyclohexanediamine, cis-	0.2 (ppm)
P-87-1882	1,4-Cyclohexanediamine, trans-	0.2 (ppm)
P-89-0867	(G) Halogenated phenyl alkane	2 (mg/m^3)
P-89-1058	Propanoic acid, 2-2-dimethyl-, ethenyl ester [CAS# 3377-92-2]	5.24 (mg/m^3)
P-90-1384	(G) Ethoxy benzothiazole disulfide	7.5 (mg/m^3)
P-90-1564	Hexanedioic acid, diethyl ester [CAS# 4074-90-2]	1 (mg/m^3)
P-90-1840	(G) Aromatic aminoether	0.03 (mg/m^3)
P-91-0222	Pentanenitrile, 3-amino- [CAS# 754105-06-0]	0.15 (ppm)
P-91-0826	Hexanoic acid, 2-ethyl, ethenyl ester [CAS# 94-04-2]	6.96 (mg/m^3)
P-92-0129	Neononanoic acid, ethenyl ester [CAS# 54423-67-5]	1 (mg/m^3)
P-92-0776	(G) Carboxylic acid glycidyl ester	0.4 (mg/m^3)
P-92-0777	(G) Carboxylic acid glycidyl ester	0.4 (mg/m^3)
P-93-0214	Calcium, bis(2,4-pentanedionato-O,O') [CAS# 19372-44-2]	4 (mg/m^3)
P-93-1694	3-(Dichloroacetyl)-5-(2-furanyl)-2,2-dimethyloxazolidine [CAS# 121776-57-6]	0.1 (mg/m^3)
P-94-1557	(G) Hydrated alkaline earth metal salts of metalloid oxyanions	5 (mg/m^3)
P-95-1098	(G) Tris carbamoyl triazine	1 (mg/m^3)
P-95-1411	(G) Substituted malonic acid, bis(substituted monoheterocycle) ester	0.3 (mg/m^3)
P-96-0019	(G) Lithiated metal oxide	0.05 (mg/m^3)

P-96-0033	Cyclopropanecarboxaldehyde [CAS# 1489-69-6]	3 (mg/m^3)
P-96-0942	Methanone, [5-[[3-(2H-benzotriazol-2-yl)-2-hydroxy-5-(1,1,3,3-tetramethylbutyl)phenyl]methyl]-2-hydroxy-4- (octyloxy)phenyl)phenyl- [CAS# 162245-07-0]	0.1 (mg/m^3)
P-96-1427	(G) Stilbene diglycidyl ether	0.5 (mg/m^3)
P-96-1428	(G) Modified polyisocyanates	0.5 (mg/m^3)
P-97-0415	2-Thiazolidinone [CAS# 2682-49-7]	0.7 (mg/m^3)
P-97-0482	Fatty acids, C_{10-13}-branched, vinyl esters [CAS# 184785-38-4]	1 (mg/m^3)
P-97-0648	Benzenamine, 3,5-difluoro- [CAS# 372-39-4]	0.4 (mg/m^3)
P-97-0649	Hydrazine carboxamide, N-(3,5diflurophenyl-) [CAS# 167412-23- 9]	0.4 (mg/m^3)
P-97-0766	(G) Organic synthesis intermediate	0.001 (mg/m^3)
P-97-1011	Oxirane,2,2'-[methylenebis[(2,6-dimethyl-4,1-phenylene)oxymethylene]]bis- [CAS# 93705-66-9]	0.35 (mg/m^3)
P-98-0002	(G) Mixed metal oxides	0.05 (mg/m^3)
P-98-0105	(G) Cycloaliphatic epoxy resin	0.3 (mg/m^3)
P-98-0823	12-aminododecanoic acid [CAS# 693-57-2]	1 (mg/m^3)
P-98-1274	(G) Silicoaluminophosphates, comd. with organic amine (P98- 1274)	0.1 (mg/m^3)
P-98-1275	Aluminosilicates, phospho- [CAS# 201167-69-3] (P98- 1275)	0.1 (mg/m^3)
P-99-0510	(G) Hexamethylenediamine adduct of substituted piperidinyloxy	0.2 (mg/m^3)
P-99-0847	(G) Mixed metal oxide	0.1 (mg/m^3)
P-00-0368	(G) Benzenesulfonamide alkylphenylsubstitutedphenylsubstitutedcarbonyl-	2.1 (mg/m^3)
P-01-0764	Magnesium potassium titanium oxide	5 (mg/m^3)
P-01-0918	(G) Substituted methoxysilane	0.05 (mg/m^3)
P-02-0214	Lithium potassium titanium oxide	0.1 (mg/m^3)
P-04-0640	(G) Diisocyanate terminated polycarbodiimide	0.05 (mg/m^3)
P-06-0036	Rutile, tin zinc, calcium-doped [CAS# 389623-01-2]	1.5 (mg/m^3)
P-06-0037	Rutile, tin zinc, sodium-doped [CAS# 389623-07-8]	1.5 (mg/m^3)
P-06-0149	Potassium titanium oxide	1.5 (mg/m^3)
P-06-0173	Lithium titanium oxide	1.5 (mg/m^3)
P-06-0702	(G) Substituted aliphatic amine	0.14 (mg/m^3)
P-07-0310	(G) Halogenated diketopyrrolopyrrol derivative	1 (mg/m^3)
P-07-0312	(G) Hexahydrophthalic anhydride, bisphenol-A, polymer with chloromethyl oxirane	1 (mg/m^3)
P-07-0537	(G) Alkanenitrile, bis(cyanoalkyl)amino	0.07 (mg/m^3)
P-07-0706	(G) Phosphonic acid ester	1 (mg/m^3)
P-08-0088	(G) Perfluorodioxyalkonic acid salt	0.01 (mg/m^3)
P-08-0508	(G) Perfluorinated aliphatic carboxylic acid	0.01 (mg/m^3)
P-08-0509	(G) Perfluorinated aliphatic carboxylic acid, ammonium salt	0.01 (mg/m^3)
P-09-0291	(G) Ammonium salt of fluorinated alkoxyfluoropropanoic acid	0.01 (mg/m^3)
P-10-0326	Propane, 1,1,1,2,3,3-hexafluoro- [CAS# 431-63-0]	3 (ppm)
P-10-0327	1-Propene, 1,2,3,3,3-pentafluoro- [CAS# 2252-83-7]	3 (ppm)
P-10-0422	Propane, 1,1,1,2,3-pentafluoro- [CAS# 431-31-2]	3 (ppm)
P-10-0455	Propane, 1,1,1,2,3,3-hexafluoro- [CAS# 431-63-0]	3 (ppm)
P-10-0457	Propane, 1,1,1,2,3-pentafluoro- [CAS#431-31-2]	3 (ppm)
P-10-0489	1-Propene, 1,2,3,3,3-pentafluoro- [CAS# 2252-83-7]	3 (ppm)
P-11-0049	(G) Alkyl phosphonic acid amine salt	3.5 (mg/m^3)
P-11-0050	(G) Alkyl phosphonic acid amine salt	10 (mg/m^3)

(G) = Generic Description of Confidential Chemical Identity

NOTE: The table linked from this page is intended to reflect legal requirements contained in TSCA section 5(e) Orders and/or section 5(a)(2) Significant New Use Rules (SNURs). This document, however, is for informational purposes only and is NOT itself legally operative, binding, or enforceable. Any discrepancies should be resolved in favor of the corresponding section 5(e) Order or section 5(a)(2) SNUR.

Local Navigation

- New Chemicals Home
- Basic Information
- PMN Forms and Information
- Premanufacture Notice Status
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- Consent Orders and Significant New Use Rules
- ECOSAR: Ecological Structural Activity Relationships
- Importing and Exporting New Chemicals

- EPA Home
- Privacy and Security Notice
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Jump to main content.

SPILMAN THOMAS & BATTLE, PLLC
ATTORNEYS AT LAW

Direct Dial: 304-340-3832
kcrockett@spilmanlaw.com

November 21, 2011

VIA HAND DELIVERY

Mr. Yogesh Patel
West Virginia Department of Environmental Protection
601 57th Street, S.E.
Charleston, WV 25304

Re: Executed Draft Consent Order No. 7418

Dear Yogesh,

Please find enclosed for your records the original copy of the above-referenced draft Consent Order, as executed on behalf of E. I. du Pont de Nemours and Company on November 18, 2011.

Should you have any questions, please do not hesitate to call me at (304) 340-3832. Thank you for your continued attention to this matter.

Very truly yours,

M. Katherine Crockett

M. Katherine Crockett

MKC:ksw

Enclosure

west virginia department of environmental protection

Division of Water and Waste Management
601 57th Street SE
Charleston, WV 25304-2345
Telephone Number: (304) 926-0495
Fax Number: (304) 926-0463

Earl Ray Tomblin, Governor
Randy C. Huffman, Cabinet Secretary
www.dep.wv.gov

CONSENT ORDER
ISSUED UNDER THE
WATER POLLUTION CONTROL ACT
WEST VIRGINIA CODE, CHAPTER 22, ARTICLE 11

TO: E. I. du Pont de Nemours and Company
Washington Works
c/o Karl J. Boelter, Plant Manager
P. O. Box 1217
Washington, WV 26181-1217

DATE: ~~11/18/2011~~

ORDER NO.: 7418

INTRODUCTION

This Consent Order is issued by the Director of the Division of Water and Waste Management, Department of Environmental Protection, (hereinafter, the "Director") under the authority of Chapter 22, Article 11, Section 1, *et. seq.* of the Code of West Virginia to E. I. du Pont de Nemours and Company (hereinafter "DuPont").

FINDINGS OF FACT

In support of this Order, the Director hereby finds the following:

1. DuPont operates a multiple product line manufacturing facility and associated industrial wastewater treatment plant located in Washington, Wood County, West Virginia. This facility is known as the Washington Works Plant ("Facility" or the "Plant").

2. This Facility is permitted under WV/NPDES Permit No. WV0001279 (the "Permit"), issued August 4, 2003 to authorize the Plant's point source discharges into the Ohio River or tributaries thereof.

3. In accordance with 47 CSR 10-4.3, DuPont timely applied for renewal of the Permit on December 20, 2007, over 180 days prior to the Permit's scheduled expiration date of June 30, 2008.

4. Since DuPont's submittal of its renewal application, WVDEP has administratively extended the Permit. As of the date of this Consent Order, the Permit remains administratively extended until December 31, 2011.

5. DuPont has developed patented technology for a new-generation processing aid for the production of high-performance fluoropolymers using a new compound C3 Dimer Acid/Salt (CAS # 13252-13-6 and CAS # 62037-80-3) (hereafter the "New Compound"). DuPont represents that this technology is a sustainable solution that includes a new processing aid with a favorable toxicological profile and rapid bioelimination. DuPont further represents that it will utilize environmental control technologies that reduce environmental release and exposure. The U.S. EPA, through a Toxic Substances Control Act Section 5(e) Consent Order ("TSCA Order") executed by DuPont on January 28, 2009, granted DuPont approval, under conditions set forth in the TSCA Order, to commercially manufacture, process, and distributes the processing aid. The TSCA Order requires that DuPont shall recover and capture (destroy) or recycle the New Compound "at an overall efficiency of 99% from all the effluent streams and the air emissions (point source and fugitive)." This requirement is interpreted by DuPont to be applied in the aggregate on an annual basis, for all U.S. sites where the New Compound is used. The wastewater treatment system for the Facility's fluoropolymers processes will be modified to achieve the TSCA Order requirements at present and future production capacity.

6. At this time, based on the results of its ongoing research and development activities, DuPont is planning to undertake construction of related upgrades to the Facility's wastewater treatment system for fluoropolymers processes currently discharging through internal Outlets 102 and 305, in conjunction with the use of the New Compound, and to commence the initial phase of commercial-scale production using the New Compound.

7. The planned upgrades to the fluoropolymers wastewater treatment system include new higher efficiency processing aid recovery, addition of a new reverse osmosis ("RO") system, and expansion of the existing carbon bed systems.

8. The Director cannot modify a WV/NPDES permit that has been administratively extended beyond its original expiration date. Accordingly, WVDEP cannot currently modify the Permit to authorize DuPont to scale up the use of the New Compound, to discharge the New Compound, and to undertake the related wastewater treatment plant upgrades described in Paragraphs 6-7, above.

9. DuPont provided toxicity data to WVDEP in March of 2011. Since that time, ongoing dialogue has occurred and additional information shared between the parties regarding the planned upgrades and the New Compound. On August 3, 2011, DuPont provided additional toxicological information as well as plans to begin production using the New Compound to the WVDEP.

10. The parties have entered into this Consent Order as the most expedient mechanism to allow DuPont to begin construction activities in connection with necessary upgrades to the wastewater treatment system and to commence commercial scale production using

the New Compound, as described in Paragraphs 5 and 6 above, pending the Director's renewal of the Permit. This Consent Order does not constitute and shall not be construed as a finding by the Director that DuPont has committed any violation(s) of the terms and conditions of the Permit.

ORDER FOR COMPLIANCE

Now, therefore, in accordance with Chapter 22, Article 11, Section 1 *et seq.* of the West Virginia Code, it is hereby ORDERED by the Director as follows:

1. DuPont shall undertake construction activities associated with the above-described wastewater treatment plant upgrades in accordance with the following schedule:

    a. Modifications to the Granular Mother Liquor ("GML")/Lamella system to achieve enhanced solids removal shall be initiated no later than six months after the effective date of this Consent Order.
    b. Construction of a new stage 1 RO unit with new membrane technology for enhanced processing aid recovery shall be initiated no later than 12 months after the effective date of this Consent Order.
    c. Sub-micron filtration and additional RO units for recovery of processing aid from previously non-recoverable process streams, and carbon beds for capture of processing aid shall be installed no later than 24 months after the effective date of this Consent Order.
    d. Additional carbon beds in W9 Line 1 for enhanced abatement capability when carbon change-outs occur shall be installed no later than 24 months after the effective date of this Consent Order.
    e. Connection of production areas to new recovery/abatement system as reflected in the permit application shall occur no later than 24 months after the effective date of this Consent Order.

2. During the period of transition to the new processing aid and treatment system upgrades, wastewaters from fluoropolymers processes covered by these changes shall continue to be treated by existing treatment facilities such that all wastestreams that are currently receiving treatment via activated carbon will continue to receive such treatment. DuPont has indicated that the New Compound will require more frequent change-outs of carbon in the carbon beds in order to maintain treatment removal efficiencies. DuPont shall replace the lead bed of granulated activated carbon within seven (7) days of detecting break-through of the New Compound from the lead bed while maintaining an effective polish bed in the system or cease discharge from the affected carbon bed system. Should monitoring detect break-through from the final polish bed, DuPont shall cease discharge from the affected carbon bed system within 24 hours of detecting such break-through until unspent carbon is in place to treat that wastestream. For purposes of this Consent Order, "break-through" will be deemed to have occurred when concentrations of the New Compound are detected at 1 mg/l or greater using the analytical method specified in Paragraph 5, below. This requirement shall apply to internal Outlets 102, 305 and a new internal monitoring location being designated as internal Outlet 605. Further, DuPont

shall operate and maintain the granulated activated carbon beds at internal Outlets 102, 305 and 605 in a manner to prevent the inhibition of treatment of other pollutants.

3. Based on the toxicological information provided and all other information available at this time, WVDEP has determined that a concentration of no more than 17.5 ug/l of the New Compound in the receiving stream outside of an applicable mixing zone will be protective of West Virginia's narrative water quality standards found in 47 CSR 2, Section 3 of the West Virginia Legislative Rules. To this end, WVDEP has established the discharge limitations for the New Compound as set out in Paragraph 4, below.

4. DuPont shall adhere to the following limitations and perform the following self-monitoring for the New Compound during the term of this Order in accordance with the following:

Outlet	Monthly Average	Maximum Daily	Units	Monitoring Frequency	Sample Type
102[A]	Monitor	Monitor	ug/l	1/day[D]	Grab
102[B]	Monitor	Monitor	ug/l	1/week[D]	Grab
305[A]	Monitor	Monitor	ug/l	1/day[D]	Grab
305[B]	Monitor	Monitor	ug/l	1/week[D]	Grab
605[A,C]	Monitor	Monitor	ug/l	1/day[D]	Grab
605[B,C]	Monitor	Monitor	ug/l	1/week[D]	Grab
002	77[E]	112[E]	ug/l	1/week	24-hour Composite
005	191[E]	278[E]	ug/l	1/week	24-hour Composite

[A] Monitoring location after exiting lead activated carbon bed and prior to entering polish activated carbon bed.
[B] Monitoring location after exiting the polish activated carbon bed.
[C] Discharge from carbon treatment system located in building 127.
[D] When discharging.
[E] As discussed in Paragraph 3, above, these limits have been calculated to ensure a concentration of no more than 17.5 ug/l in the receiving stream outside of the applicable mixing zone, as determined by application of the mixing zone dilution factor for the respective outlet specified in the current Fact Sheet for the Permit.

5. Samples taken at Outlets 002 and 005 pursuant to Paragraph 4 above shall be analyzed by Liquid Chromatography/Mass Spectrometry/Mass Spectrometry ("LC/MS/MS") with a method detection limit ("MDL") of 1 ug/l or less. Samples taken at internal Outlets 102, 305 and 605 pursuant to Paragraph 4 above shall be analyzed by Liquid Chromatography ("LC") or Gas Chromatography ("GC") per internal plant method with an MDL of 1 mg/l or less.

6. Outlet results for sampling performed pursuant to Paragraph 4 above shall be reported monthly to the WVDEP on the attached Discharge Monitoring Reports ("DMRs"). In addition, DuPont shall maintain a log of the results of the daily monitoring required by Paragraph 4 at internal Outlets 102, 305 and 605, and shall submit this log to WVDEP on a monthly basis as an attachment to its DMR.

7. Commercial production using the New Compound and generating wastewaters for on-site treatment may commence upon the execution of this Order, subject to compliance with the provisions of this Order.

8. This Consent Order may be reopened and revised by agreement of the parties to prescribe additional and/or different requirements, including different monitoring requirements and/or increased or decreased discharge limitations, pursuant to any new information or data regarding the New Compound.

9. This Order shall terminate upon notification by DuPont that the actions required by the Order of Compliance have been completed and the Director's written concurrence therewith or upon the issuance by WVDEP of a renewed permit for the Facility that authorizes the activities covered by this Order that have not been completed as of that time, whichever occurs earlier.

OTHER PROVISIONS

1. DuPont hereby waives its right to appeal this Order under the provisions of Chapter 22, Article 11, Section 21 of the Code of West Virginia. Under this Order, DuPont agrees to take all actions required by the terms and conditions of this Order and consents to and will not contest the Director's jurisdiction regarding this Order. However, DuPont does not admit to any factual and legal determinations made by the Director and reserves all rights and defenses available regarding liability or responsibility in any proceedings regarding DuPont other than proceedings, administrative or civil, to enforce this Order.

2. If any event occurs which causes delay in the achievement of the requirements of this Order, DuPont shall have the burden of proving that the delay was caused by circumstances beyond its reasonable control which could not have been overcome by due diligence (i.e., force majeure). Force majeure shall not include delays caused or contributed to by the lack of sufficient funding. Within three (3) working days after DuPont becomes aware of such a delay, DuPont shall provide written notification to the Director. Within ten (10) working days of initial notification, DuPont shall submit a detailed written explanation of the anticipated length and cause of the delay, the measures taken and/or to be taken to prevent or minimize the delay, and a timetable by which DuPont intends to implement these measures. If the Director agrees that the delay has been or will be caused by circumstances beyond the reasonable control of DuPont (i.e., force majeure), the time for performance hereunder shall be extended for a period of time equal to the delay resulting from such circumstances. A force majeure amendment

granted by the Director shall be considered a binding extension of this Order and of the requirements herein. The determination of the Director shall be final and not subject to appeal.

3. Compliance with the terms and conditions of this Order shall not in any way be construed as relieving DuPont of the obligation to comply with any applicable law, permit, other order, or any other requirement otherwise applicable. Violations of the terms and conditions of this Order may subject DuPont to additional penalties and injunctive relief in accordance with the applicable law.

4. The provisions of this Order are severable and should a court or board of competent jurisdiction declare any provisions to be invalid or unenforceable, all other provisions shall remain in full force and effect.

5. This Order is binding on DuPont, its successors and assigns.

This Order shall become effective upon the date on which a true and correct copy of this fully executed Order is received by DuPont.

Karl J. Boelter, Plant Manager
Washington Works
E. I. du Pont de Nemours and Company

11/18/11
Date

Public Notice begin: _____
Date

Public Notice end: _____
Date

Scott G. Mandirola, Director
Division of Water and Waste Management
West Virginia Department of Environmental Protection

Date

SGM:rt/mls

Enclosure(s)
cc: Environmental Inspector
Environmental Inspector Supervisor
EPA Region III

Submit Time: 12/1/2011 16:54:29
From: CN=Benjamin Bahk/OU=DC/O=USEPA/C=US
To: CN=Clarke Thurmon/OU=DC/O=USEPA/C=US@EPA
Cc:
Subject: Fw: From Ohio/West Virginia -- New DuPont/WVDEP Consent Order for New PFCs

Hi Clarke,

fyi

Ben Bahk
U.S. Environmental Protection Agency
Office of Civil Enforcement
1200 Pennsylvania Ave. NW Mail Code 2243A
Washington, DC 20460
202.564.4293 (office)
202.564.0024 (fax)

Help eliminate environmental violations - report tips and complaints at:

http://www.epa.gov/compliance/complaints/index.html

----- Forwarded by Benjamin Bahk/DC/USEPA/US on 12/01/2011 11:54 AM -----

> From: Mark Garvey/DC/USEPA/US
> To: David Lynch/DC/USEPA/US@EPA, Benjamin Bahk/DC/USEPA/US@EPA, Laurence Libelo/DC/USEPA/US@EPA
> Date: 11/29/2011 10:12 AM
> Subject: Fw: From Ohio/West Virginia -- New DuPont/WVDEP Consent Order for New PFCs

---

David, Laurence and Ben,

The Citizen's Suit attorney - Rob Billot involved in the PFOA TSCA 8(e) case in 2005, is sending a WV Order below.

Mark

Mark Garvey
Attorney
202-564-4168
US EPA
Office of Civil Enforcement
Garvey.Mark@epa.gov

----- Forwarded by Mark Garvey/DC/USEPA/US on 11/29/2011 10:09 AM -----

From: "Bilott, Robert A." <bilott@taftlaw.com>
To: Mark Garvey/DC/USEPA/US@EPA, Ilana Saltzbart/DC/USEPA/US@EPA
Date: 11/29/2011 10:04 AM
Subject: New DuPont/WVDEP Consent Order for New PFCs

FYI

Taft /

Robert A. Bilott / Partner
Taft Stettinius & Hollister LLP
425 Walnut Street, Suite 1800
Cincinnati, Ohio 45202-3957
Tel: 513.381.2838 • Fax: 513.381.0205
Direct: 513.357.9638 • Cell: Personal Phone / Ex. 6
www.taftlaw.com / bilott@taftlaw.com

###
-----Original Message-----
From: dep.online@wv.gov [mailto:dep.online@wv.gov]
Sent: Monday, November 28, 2011 10:10 AM
To: Bilott, Robert A.
Subject: DEP Public Notice - County - Wood - Applicant - E I DuPont De Nemours & Co - Application No. WV0001279

The following was sent to you because you are a
Member of the DEP Public Notice mailing list.

==========
Monday, November 28, 2011 @ 10:09 AM
==========

STATE OF WEST VIRGINIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
DIVISION OF WATER AND WASTE MANAGEMENT

PUBLIC NOTICE

WEST VIRGINIA DEPARTMENT OF ENVIRONMENTAL PROTECTION'S, PUBLIC INFORMATION OFFICE, 601 57TH STREET SE, CHARLESTON, WEST VIRGINIA 25304-2345 TELEPHONE: (304) 926-0440.

INTENT TO ENTER AN ADMINISTRATIVE CONSENT ORDER UNDER THE WEST VIRGINIA WATER POLLUTION CONTROL ACT

Public Notice No.: L-136-11 Public Notice
Date: November 26, 2011

Paper: Parkersburg News

The following has been agreed to by The WV Department of Environmental Protection (WVDEP) and E I DuPont Nemours & Co. to the terms and conditions of a Consent Order for this facility or activity:

Permit No.: WV0001279

Order No: 7418

Permittee: E I DUPONT DE NEMOURS & CO
PO BOX 1217
WASHINGTON, WV 26181

Location: WASHINGTON, WOOD COUNTY

Latitude: 39:16:19 Longitude: 81:39:42

Receiving Stream:
OHIO RIVER

Activity:

The WV Department of Environmental Protection (WVDEP) and E I DuPont Nemours & Co. have proposed an Administrative Consent Order that will allow DuPont to begin construction activities in connection with necessary upgrades to the waste water treatment system and to commence commercial scale production using their new patented technology for a new processing aid for the production of high-performance fluoropolymers using a new compound.

Business conducted:

Production of polymer resins; compounded plastics; nylon fibers; formaldehyde; fluorocarbon polymers, monomers, telomers; and calcium fluoride.

Implementation:

Compliance shall be attained through the issuance of Order No. 7418, and any revisions, thereto.

On the basis of review of the materials, the "Water Pollution Control Act (Chapter 22, Article 11-8(a))," and the "West Virginia Legislative Rules," the State of West Virginia will act on the above action.

Any interested person may submit written comments on the draft Order and may request a public hearing by addressing such to the Director of the Division of Water and Waste Management within 30 days of the date of the public notice. Such comments or requests should be addressed to:
Director, Division of Water and Waste Management, DEP
ATTN: Lori Devereux, Permitting Section
601 57th Street SE
Charleston, WV 25304-2345

The public comment period begins November 26, 2011 ends December 26, 2011.

Comments received within this period will be considered prior to acting on the Order. Correspondence should include the name, address and the telephone number of the writer and a concise statement of the nature of the issues rose. The Director shall hold a public hearing whenever a finding is made, on the basis of requests, that there is a significant degree of public interest on issues relevant to the draft Order(s). Interested persons may contact the public information office to obtain further information.

The draft Order and any pertinent data may be inspected, by appointment, at the Division of Water and Waste Management Public Information Office, at 601 57th Street SE, Charleston, WV 25304-2345, between 8:00 a.m. and 4:00 p.m. on business days. Copies of the documents may be obtained from the Division at a nominal cost. Individuals requiring Telecommunication Device (TDD) may contact our agency by calling (304) 926-0493. Calls must be made 8:30 a.m. to 4:30 p.m. Monday through Friday.

==========
To view past notices of open public comment periods or to unsubscribe from this Mailing List, login at:
http://apps.dep.wv.gov//MLists2/

DuPont Final Version.pdf  DuPont Final Version.pdf

From: "Bilott, Robert A." <bilott@taftlaw.com>
To: Mark Garvey/DC/USEPA/US@EPA Ilana Saltzbart/DC/USEPA/US@EPA
Submit Time: 11/29/2011 15:04:02
Subject: New DuPont/WVDEP Consent Order for New PFCs

FYI

Taft /

Robert A. Bilott / Partner
Taft Stettinius & Hollister LLP
425 Walnut Street, Suite 1800
Cincinnati, Ohio 45202-3957
Tel: 513.381.2838 • Fax: 513.381.0205
Direct: 513.357.9638 • Cell: Personal Phone / Ex. 6
www.taftlaw.com / bilott@taftlaw.com

###
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DIVISION OF WATER AND WASTE MANAGEMENT

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TELEPHONE:
(304) 926-0440.

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Mailing List, login at:
http://apps.dep.wv.gov//MLists2/

DuPont Final Version.pdf 

SPILMAN THOMAS & BATTLE, PLLC
ATTORNEYS AT LAW

Direct Dial: 304-340-3832
kcrockett@spilmanlaw.com

November 21, 2011

VIA HAND DELIVERY

Mr. Yogesh Patel
West Virginia Department of Environmental Protection
601 57th Street, S.E.
Charleston, WV 25304

Re: Executed Draft Consent Order No. 7418

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Very truly yours,

M. Katherine Crockett

M. Katherine Crockett

MKC:ksw

Enclosure

west virginia department of environmental protection

Division of Water and Waste Management
601 57th Street SE
Charleston, WV 25304-2345
Telephone Number: (304) 926-0495
Fax Number: (304) 926-0463

Earl Ray Tomblin, Governor
Randy C. Huffman, Cabinet Secretary
www.dep.wv.gov

CONSENT ORDER
ISSUED UNDER THE
WATER POLLUTION CONTROL ACT
WEST VIRGINIA CODE, CHAPTER 22, ARTICLE 11

TO: E. I. du Pont de Nemours and Company
Washington Works
c/o Karl J. Boelter, Plant Manager
P. O. Box 1217
Washington, WV 26181-1217

DATE: ~~11/18/2011~~

ORDER NO.: 7418

INTRODUCTION

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FINDINGS OF FACT

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5. DuPont has developed patented technology for a new-generation processing aid for the production of high-performance fluoropolymers using a new compound C3 Dimer Acid/Salt (CAS # 13252-13-6 and CAS # 62037-80-3) (hereafter the "New Compound"). DuPont represents that this technology is a sustainable solution that includes a new processing aid with a favorable toxicological profile and rapid bioelimination. DuPont further represents that it will utilize environmental control technologies that reduce environmental release and exposure. The U.S. EPA, through a Toxic Substances Control Act Section 5(e) Consent Order ("TSCA Order") executed by DuPont on January 28, 2009, granted DuPont approval, under conditions set forth in the TSCA Order, to commercially manufacture, process, and distributes the processing aid. The TSCA Order requires that DuPont shall recover and capture (destroy) or recycle the New Compound "at an overall efficiency of 99% from all the effluent streams and the air emissions (point source and fugitive)." This requirement is interpreted by DuPont to be applied in the aggregate on an annual basis, for all U.S. sites where the New Compound is used. The wastewater treatment system for the Facility's fluoropolymers processes will be modified to achieve the TSCA Order requirements at present and future production capacity.

6. At this time, based on the results of its ongoing research and development activities, DuPont is planning to undertake construction of related upgrades to the Facility's wastewater treatment system for fluoropolymers processes currently discharging through internal Outlets 102 and 305, in conjunction with the use of the New Compound, and to commence the initial phase of commercial-scale production using the New Compound.

7. The planned upgrades to the fluoropolymers wastewater treatment system include new higher efficiency processing aid recovery, addition of a new reverse osmosis ("RO") system, and expansion of the existing carbon bed systems.

8. The Director cannot modify a WV/NPDES permit that has been administratively extended beyond its original expiration date. Accordingly, WVDEP cannot currently modify the Permit to authorize DuPont to scale up the use of the New Compound, to discharge the New Compound, and to undertake the related wastewater treatment plant upgrades described in Paragraphs 6-7, above.

9. DuPont provided toxicity data to WVDEP in March of 2011. Since that time, ongoing dialogue has occurred and additional information shared between the parties regarding the planned upgrades and the New Compound. On August 3, 2011, DuPont provided additional toxicological information as well as plans to begin production using the New Compound to the WVDEP.

10. The parties have entered into this Consent Order as the most expedient mechanism to allow DuPont to begin construction activities in connection with necessary upgrades to the wastewater treatment system and to commence commercial scale production using

the New Compound, as described in Paragraphs 5 and 6 above, pending the Director's renewal of the Permit. This Consent Order does not constitute and shall not be construed as a finding by the Director that DuPont has committed any violation(s) of the terms and conditions of the Permit.

ORDER FOR COMPLIANCE

Now, therefore, in accordance with Chapter 22, Article 11, Section 1 *et seq.* of the West Virginia Code, it is hereby ORDERED by the Director as follows:

1. DuPont shall undertake construction activities associated with the above-described wastewater treatment plant upgrades in accordance with the following schedule:

    a. Modifications to the Granular Mother Liquor ("GML")/Lamella system to achieve enhanced solids removal shall be initiated no later than six months after the effective date of this Consent Order.
    b. Construction of a new stage 1 RO unit with new membrane technology for enhanced processing aid recovery shall be initiated no later than 12 months after the effective date of this Consent Order.
    c. Sub-micron filtration and additional RO units for recovery of processing aid from previously non-recoverable process streams, and carbon beds for capture of processing aid shall be installed no later than 24 months after the effective date of this Consent Order.
    d. Additional carbon beds in W9 Line 1 for enhanced abatement capability when carbon change-outs occur shall be installed no later than 24 months after the effective date of this Consent Order.
    e. Connection of production areas to new recovery/abatement system as reflected in the permit application shall occur no later than 24 months after the effective date of this Consent Order.

2. During the period of transition to the new processing aid and treatment system upgrades, wastewaters from fluoropolymers processes covered by these changes shall continue to be treated by existing treatment facilities such that all wastestreams that are currently receiving treatment via activated carbon will continue to receive such treatment. DuPont has indicated that the New Compound will require more frequent change-outs of carbon in the carbon beds in order to maintain treatment removal efficiencies. DuPont shall replace the lead bed of granulated activated carbon within seven (7) days of detecting break-through of the New Compound from the lead bed while maintaining an effective polish bed in the system or cease discharge from the affected carbon bed system. Should monitoring detect break-through from the final polish bed, DuPont shall cease discharge from the affected carbon bed system within 24 hours of detecting such break-through until unspent carbon is in place to treat that wastestream. For purposes of this Consent Order, "break-through" will be deemed to have occurred when concentrations of the New Compound are detected at 1 mg/l or greater using the analytical method specified in Paragraph 5, below. This requirement shall apply to internal Outlets 102, 305 and a new internal monitoring location being designated as internal Outlet 605. Further, DuPont

shall operate and maintain the granulated activated carbon beds at internal Outlets 102, 305 and 605 in a manner to prevent the inhibition of treatment of other pollutants.

3. Based on the toxicological information provided and all other information available at this time, WVDEP has determined that a concentration of no more than 17.5 ug/l of the New Compound in the receiving stream outside of an applicable mixing zone will be protective of West Virginia's narrative water quality standards found in 47 CSR 2, Section 3 of the West Virginia Legislative Rules. To this end, WVDEP has established the discharge limitations for the New Compound as set out in Paragraph 4, below.

4. DuPont shall adhere to the following limitations and perform the following self-monitoring for the New Compound during the term of this Order in accordance with the following:

Outlet	Monthly Average	Maximum Daily	Units	Monitoring Frequency	Sample Type
102[A]	Monitor	Monitor	ug/l	1/day[D]	Grab
102[B]	Monitor	Monitor	ug/l	1/week[D]	Grab
305[A]	Monitor	Monitor	ug/l	1/day[D]	Grab
305[B]	Monitor	Monitor	ug/l	1/week[D]	Grab
605[A,C]	Monitor	Monitor	ug/l	1/day[D]	Grab
605[B,C]	Monitor	Monitor	ug/l	1/week[D]	Grab
002	77[E]	112[E]	ug/l	1/week	24-hour Composite
005	191[E]	278[E]	ug/l	1/week	24-hour Composite

[A] Monitoring location after exiting lead activated carbon bed and prior to entering polish activated carbon bed.
[B] Monitoring location after exiting the polish activated carbon bed.
[C] Discharge from carbon treatment system located in building 127.
[D] When discharging.
[E] As discussed in Paragraph 3, above, these limits have been calculated to ensure a concentration of no more than 17.5 ug/l in the receiving stream outside of the applicable mixing zone, as determined by application of the mixing zone dilution factor for the respective outlet specified in the current Fact Sheet for the Permit.

5. Samples taken at Outlets 002 and 005 pursuant to Paragraph 4 above shall be analyzed by Liquid Chromatography/Mass Spectrometry/Mass Spectrometry ("LC/MS/MS") with a method detection limit ("MDL") of 1 ug/l or less. Samples taken at internal Outlets 102, 305 and 605 pursuant to Paragraph 4 above shall be analyzed by Liquid Chromatography ("LC") or Gas Chromatography ("GC") per internal plant method with an MDL of 1 mg/l or less.

6. Outlet results for sampling performed pursuant to Paragraph 4 above shall be reported monthly to the WVDEP on the attached Discharge Monitoring Reports ("DMRs"). In addition, DuPont shall maintain a log of the results of the daily monitoring required by Paragraph 4 at internal Outlets 102, 305 and 605, and shall submit this log to WVDEP on a monthly basis as an attachment to its DMR.

7. Commercial production using the New Compound and generating wastewaters for on-site treatment may commence upon the execution of this Order, subject to compliance with the provisions of this Order.

8. This Consent Order may be reopened and revised by agreement of the parties to prescribe additional and/or different requirements, including different monitoring requirements and/or increased or decreased discharge limitations, pursuant to any new information or data regarding the New Compound.

9. This Order shall terminate upon notification by DuPont that the actions required by the Order of Compliance have been completed and the Director's written concurrence therewith or upon the issuance by WVDEP of a renewed permit for the Facility that authorizes the activities covered by this Order that have not been completed as of that time, whichever occurs earlier.

OTHER PROVISIONS

1. DuPont hereby waives its right to appeal this Order under the provisions of Chapter 22, Article 11, Section 21 of the Code of West Virginia. Under this Order, DuPont agrees to take all actions required by the terms and conditions of this Order and consents to and will not contest the Director's jurisdiction regarding this Order. However, DuPont does not admit to any factual and legal determinations made by the Director and reserves all rights and defenses available regarding liability or responsibility in any proceedings regarding DuPont other than proceedings, administrative or civil, to enforce this Order.

2. If any event occurs which causes delay in the achievement of the requirements of this Order, DuPont shall have the burden of proving that the delay was caused by circumstances beyond its reasonable control which could not have been overcome by due diligence (i.e., force majeure). Force majeure shall not include delays caused or contributed to by the lack of sufficient funding. Within three (3) working days after DuPont becomes aware of such a delay, DuPont shall provide written notification to the Director. Within ten (10) working days of initial notification, DuPont shall submit a detailed written explanation of the anticipated length and cause of the delay, the measures taken and/or to be taken to prevent or minimize the delay, and a timetable by which DuPont intends to implement these measures. If the Director agrees that the delay has been or will be caused by circumstances beyond the reasonable control of DuPont (i.e., force majeure), the time for performance hereunder shall be extended for a period of time equal to the delay resulting from such circumstances. A force majeure amendment

granted by the Director shall be considered a binding extension of this Order and of the requirements herein. The determination of the Director shall be final and not subject to appeal.

3. Compliance with the terms and conditions of this Order shall not in any way be construed as relieving DuPont of the obligation to comply with any applicable law, permit, other order, or any other requirement otherwise applicable. Violations of the terms and conditions of this Order may subject DuPont to additional penalties and injunctive relief in accordance with the applicable law.

4. The provisions of this Order are severable and should a court or board of competent jurisdiction declare any provisions to be invalid or unenforceable, all other provisions shall remain in full force and effect.

5. This Order is binding on DuPont, its successors and assigns.

This Order shall become effective upon the date on which a true and correct copy of this fully executed Order is received by DuPont.

Karl J. Boelter, Plant Manager
Washington Works
E. I. du Pont de Nemours and Company

11/18/11
Date

Public Notice begin: _____
Date

Public Notice end: _____
Date

Scott G. Mandirola, Director
Division of Water and Waste Management
West Virginia Department of Environmental Protection

Date

SGM:rt/mls

Enclosure(s)
cc: Environmental Inspector
Environmental Inspector Supervisor
EPA Region III

Agenda

OCE Weekly – AA/DAA

Conference Call Number: **Personal Phone / Ex. 6**

Conference Room - 3216 WJC South

1:00 PM –2:00 PM

Monday, December 11, 2017

1) Jack Noble – WED and Region 9

2) Chemours Update – WCED, WED and Regions

Deliberative Process / Ex. 5 / Law Enforcement / Ex. 7(a)

Deliberative Process / Ex. 5 / Law Enforcement / Ex. 7(a)

Deliberative Process / Ex. 5 / Law Enforcement / Ex. 7(a)

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Deliberative Process / Ex. 5 / Law Enforcement / Ex. 7(a)

Deliberative Process / Ex. 5 / Law Enforcement / Ex. 7(a)

OCSPP Was GenX used in a manner that was incompatible with the consent agreement under the Toxic Substances Control Act

OPPT and Chemours signed a Section 5(e) Consent order in 2009 for P-08-0508/0509. The

Deliberative Process / Ex. 5

The terms of the 2009 Consent Order included:

a. Any workers who may be exposed must wear chemically impervious gloves
b. Any workers exposed to P-08-0508 via inhalation must wear a respirator with a NIOSH APF of "3,000"
c. Any workers exposed to P-08-0509 via inhalation must wear an appropriate NIOSH-approved respirator (APF not specified)
d. As an alternate to using respirators, a NCEL of 0.01 mg/m3 (based on APFO) may be used for the PMN substances.
e. For operations in the US, the PMN substances must be recovered and captured (destroyed) or recycled from all process wastewater effluent streams and air emissions(point source and fugitive) at an overall efficiency of 99%.
f. Distribute the polymers containing residual PMN substances at levels not to exceed 200 ppb.

In 2012-2013, DuPont and EPA communicated about PPE modifications. Based on the NCEL, DuPont requested approval for respirators with an APF of 50, to be used when the air concentration of P-08-0508/0509 does not exceed 50 times the NCEL. The maximum use concentration was set at 0.0365 ppm, and EPA approved the request.

Deliberative Process / Ex. 5

To: Theis, Joseph[Theis.Joseph@epa.gov]
Cc: Sullivan, Greg[Sullivan.Greg@epa.gov]; Kelley, Rosemarie[Kelley.Rosemarie@epa.gov]; Fogarty, Johnpc[Fogarty.Johnpc@epa.gov]; Miles, James[miles.james@epa.gov]; Saenz, Diana[Saenz.Diana@epa.gov]; Speir, Jeffrey[speir.jeffrey@epa.gov]; Denton, Loren[Denton.Loren@epa.gov]; Bahk, Benjamin[Bahk.Benjamin@epa.gov]
From: Pollins, Mark
Sent: Sat 6/2/2018 2:38:40 PM
Subject: Re: Notice of Intent - TSCA citizen suit

We discussed this a bit during the WCED and WED meeting on the matter. Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5 We can discuss on Monday.

Sent from my iPhone

On Jun 2, 2018, at 9:43 AM, Theis, Joseph <Theis.Joseph@epa.gov> wrote:

Mark and Greg,

Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5

On Jun 1, 2018, at 1:02 PM, Sullivan, Greg <Sullivan.Greg@epa.gov> wrote:

Rosemarie,

FYI – Here is an update and our planned next steps.

We met with WED yesterday. **Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5**

Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5

Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5

From: Palmer, Leif
Sent: Tuesday, May 29, 2018 2:16 PM
To: Kelley, Rosemarie <Kelley.Rosemarie@epa.gov>
Cc: Rubini, Suzanne <Rubini.Suzanne@epa.gov>; Sullivan, Greg <Sullivan.Greg@epa.gov>
Subject: Fwd: Notice of Intent - TSCA citizen suit

Hi — our internet is out. Please see the email from DOJ. Greg, I left you a voicemail about this.

Sent from my iPhone
Begin forwarded message:

> **From:** "Mann, Martha (ENRD)" <Martha.Mann@usdoj.gov>
> **Date:** May 29, 2018 at 11:54:34 AM EDT
> **To:** "palmer.leif@epa.gov" <palmer.leif@epa.gov>, "Grant.Brian@epa.gov" <Grant.Brian@epa.gov>
> **Cc:** "Cirino, Paul (ENRD)" <Paul.Cirino@usdoj.gov>
> **Subject: Notice of Intent - TSCA citizen suit**
>
> Hello Leif and Brian,
>
> Just checking in to see if you are aware of the attached notice of intent, and whether you have assigned the matter to an attorney in your office.

Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5

> Thanks so much,
> Martha
>
> Martha C. Mann
> United States Department of Justice
> Environment and Natural Resources Division
> 202.514.2664

To: Garvey, Mark[Garvey.Mark@epa.gov]; Ellis, Tony[Ellis.Tony@epa.gov]
From: Miles, James
Sent: Fri 6/1/2018 6:29:10 PM
Subject: FW: Notice of Intent - TSCA citizen suit

I'll set up a meeting to discuss Monday. Highlighting a few things.

From: Sullivan, Greg
Sent: Friday, June 01, 2018 1:02 PM
To: Kelley, Rosemarie <Kelley.Rosemarie@epa.gov>
Cc: Theis, Joseph <Theis.Joseph@epa.gov>; Fogarty, Johnpc <Fogarty.Johnpc@epa.gov>; Miles, James <miles.james@epa.gov>; Saenz, Diana <Saenz.Diana@epa.gov>
Subject: FW: Notice of Intent - TSCA citizen suit

Rosemarie,

FYI – Here is an update and our planned next steps.

We met with WED yesterday. **Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5**

Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5

From: Palmer, Leif
Sent: Tuesday, May 29, 2018 2:16 PM
To: Kelley, Rosemarie <Kelley.Rosemarie@epa.gov>
Cc: Rubini, Suzanne <Rubini.Suzanne@epa.gov>; Sullivan, Greg <Sullivan.Greg@epa.gov>
Subject: Fwd: Notice of Intent - TSCA citizen suit

Hi — our internet is out. Please see the email from DOJ. Greg, I left you a voicemail about this.

Sent from my iPhone
Begin forwarded message:

From: "Mann, Martha (ENRD)" <Martha.Mann@usdoj.gov>

Date: May 29, 2018 at 11:54:34 AM EDT
To: "palmer.leif@epa.gov" <palmer.leif@epa.gov>, "Grant.Brian@epa.gov" <Grant.Brian@epa.gov>
Cc: "Cirino, Paul (ENRD)" <Paul.Cirino@usdoj.gov>
Subject: Notice of Intent - TSCA citizen suit

Hello Leif and Brian,

Just checking in to see if you are aware of the attached notice of intent, and whether you have assigned the matter to an attorney in your office.

Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5

Thanks so much,
Martha

Martha C. Mann
United States Department of Justice
Environment and Natural Resources Division
202.514.2664

To: Miles, James[miles.james@epa.gov]
Cc: Libelo, Laurence[Libelo.Laurence@epa.gov]; Lindstrom, Andrew[Lindstrom.Andrew@epa.gov]; Strynar, Mark[strynar.mark@epa.gov]; Speir, Jeffrey[speir.jeffrey@epa.gov]
From: Garvey, Mark
Sent: Mon 10/23/2017 2:27:14 PM
Subject: RE: Enforcement/Investigatory / Ex. 7(a)
sanitized_consent_order_p_08_0508_and_0509 (006).pdf

James,

I'm attaching the DuPont/Chemours TSCA 5(e) Consent Order sanitized version. There are numerous statements made in the 5(e) Order relating to the requirement to limit air emissions to an overall efficiency of 99%. I'm pasting below several of those statements.

Pages iii. & iv

II. SUMMARY OF TERMS OF THE ORDER

The Consent Order for these PMN substances requires the Company to:

(f) for operations in the United States, recover and capture (destroy) or recycle the PMN substances from all the process wastewater effluent streams and air emissions (point source and fugitive) at an overall efficiency of 99% and distribute only to those customers that achieve this percentage of efficiency or destruction;

Page xiv

Releases to the environment were estimated to water and to air (fugitive) and to air via incineration. Based on submitter information, the Company currently collects the waste containing the PMN substances and sends the waste to an off-site RCRA incinerator. In the future, the Company intends to develop and use methods to recapture and/or recycle the substances, but is not now doing so. EPA requires in the attached Consent Order that the substances be recovered, recycled and/or destroyed at levels achieving 99% efficiency. EPA will require that the Company directly sell the substances only to customers, if any, that achieve comparable recovery or destruction.

Page 36

CONTROL OF EFFLUENT & EMISSIONS

(a) The Company shall recover and capture (destroy) or recycle the PMN substances at an overall efficiency of 99% from all the effluent process streams and the air emissions (point source and fugitive).

Mark Garvey
EPA Headquarters
Office of Civil Enforcement
Attorney
202-564-4168
garvey.mark@epa.gov

From: Garvey, Mark
Sent: Thursday, October 19, 2017 11:51 AM
To: Miles, James <miles.james@epa.gov>
Cc: Libelo, Laurence <Libelo.Laurence@epa.gov>; Lindstrom, Andrew <Lindstrom.Andrew@epa.gov>; Strynar, Mark <strynar.mark@epa.gov>; Speir, Jeffrey <speir.jeffrey@epa.gov>

Subject: FW: Enforcement/Investigatory / Ex. 7(a)

Enforcement/Investigatory / Ex. 7(a)

Mark

Mark Garvey
EPA Headquarters
Office of Civil Enforcement
Attorney
202-564-4168
garvey.mark@epa.gov

From: Tucker, Marlene
Sent: Thursday, October 19, 2017 9:45 AM
To: Garvey, Mark <Garvey.Mark@epa.gov>
Subject: FW: data requested

Mark,

Enforcement/Investigatory / Ex. 7(a)

Regards

Marlene Tucker

From: Bookman, Robert
Sent: Wednesday, October 18, 2017 11:55 AM
To: Tucker, Marlene <Tucker.Marlene@epa.gov>
Subject: FW: data requested

Marlene, FYI.

Robert

From: Allenbach, Becky
Sent: Wednesday, October 18, 2017 11:50 AM
To: Mitchell, Ken <Mitchell.Ken@epa.gov>
Cc: Doa, Maria <Doa.Maria@epa.gov>; George, Verne <George.Verne@epa.gov>; Bates, Keith <Bates.Keith@epa.gov>; Bookman, Robert <Bookman.Robert@epa.gov>; Kemker, Carol <Kemker.Carol@epa.gov>
Subject: Re: data requested

Maria, as explained by NC yesterday, Enforcement/Investigatory / Ex. 7(a)

Enforcement/Investigatory / Ex. 7(a)

Becky B. Allenbach, Chief
Grants and Drinking Water Protection Branch
Water Protection Division - Region 4

On Oct 18, 2017, at 11:45 AM, Mitchell, Ken <Mitchell.Ken@epa.gov> wrote:

Maria...please find attached air emission data requested by NC and provided by Chemours. Please let us know if you have any questions.

Kenneth L. Mitchell, Ph.D. | Special Assistant to the Director |
Air, Pesticides, and Toxics Management Division
U.S. Environmental Protection Agency | 61 Forsyth Street, SW | Atlanta, GA 30303
Voice: 404-562-9065 | Fax: 404-562-9066 | Email: mitchell.ken@epa.gov

From: Allenbach, Becky
Sent: Tuesday, October 17, 2017 7:30 PM
To: Kemker, Carol <Kemker.Carol@epa.gov>; Mitchell, Ken <Mitchell.Ken@epa.gov>
Subject: FW: data requested

Carol and Ken:

This was discussed on our weekly check in with NC. **Enforcement/Investigatory / Ex. 7(a)** I was hoping you could share this with your HQ TSCA counterparts. I can fill in info if needed.

Becky

Becky B. Allenbach, Chief
Grants and Drinking Water Protection Branch
Water Protection Division
EPA Region 4 - Atlanta
Office: 404-562-9687
Cell: **Personal Phone / Ex. 6**

From: Culpepper, Linda [mailto:linda.culpepper@ncdenr.gov]
Sent: Tuesday, October 17, 2017 4:08 PM
To: Buckley, Timothy <Buckley.Timothy@epa.gov>; Strynar, Mark <Strynar.Mark@epa.gov>; Lindstrom, Andrew <Lindstrom.Andrew@epa.gov>; Allenbach, Becky <Allenbach.Becky@epa.gov>; Kemker, Carol <Kemker.Carol@epa.gov>; Mitchell, Ken <Mitchell.Ken@epa.gov>; Banister, Beverly <Banister.Beverly@epa.gov>; Jones, Aaryn <Jones.Aaryn@epa.gov>; France, Danny <France.Danny@epa.gov>
Cc: Scott, Michael <michael.scott@ncdenr.gov>; Woosley, Julie <julie.woosley@ncdenr.gov>; Johnson, Chris <chris.johnson@ncdenr.gov>; Cox, Heidi <heidi.cox@ncdenr.gov>; Allen, Trent <trent.allen@ncdenr.gov>; Gregson, Jim <jim.gregson@ncdenr.gov>; michael.abraczinskas@ncdenr.gov
Subject: FW: data requested

Forwarding air emissions data.

Linda Culpepper
Deputy Director
Division of Water Resources
North Carolina Department of Environmental Quality

1611 Mail Service Center
Phone: 919-707-9014

From: Abraczinskas, Michael
Sent: Tuesday, October 17, 2017 3:55 PM
To: Culpepper, Linda <linda.culpepper@ncdenr.gov>
Subject: data requested

Linda,
Attached you'll find the emissions data requested by EPA today. Please pass along to the points of contact.
Thanks!
-Mike

Mike Abraczinskas, EIT, CPM
Director, Division of Air Quality
North Carolina Department of Environmental Quality

919 707 8447 office
michael.abraczinskas@ncdenr.gov

217 West Jones Street
1641 Mail Service Center
Raleigh, NC 27699

<image001.png>

Email correspondence to and from this address is subject to the North Carolina Public Records Law and may be disclosed to third parties.

<DEQ Emissions Information Dimer Acid.docx>

To: Miles, James[miles.james@epa.gov]
Cc: Libelo, Laurence[Libelo.Laurence@epa.gov]; Lindstrom, Andrew[Lindstrom.Andrew@epa.gov]; Strynar, Mark[strynar.mark@epa.gov]; Speir, Jeffrey[speir.jeffrey@epa.gov]
From: Garvey, Mark
Sent: Thur 10/19/2017 3:51:09 PM
Subject: FW: Enforcement/Investigatory / Ex. 7(a)

Enforcement/Investigatory / Ex. 7(a)

Mark

Mark Garvey
EPA Headquarters
Office of Civil Enforcement
Attorney
202-564-4168
garvey.mark@epa.gov

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Enforcement/Investigatory / Ex. 7(a)

Regards

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Subject: FW: data requested

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Robert

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Cc: Doa, Maria <Doa.Maria@epa.gov>; George, Verne <George.Verne@epa.gov>; Bates, Keith <Bates.Keith@epa.gov>; Bookman, Robert <Bookman.Robert@epa.gov>; Kemker, Carol <Kemker.Carol@epa.gov>
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Enforcement/Investigatory / Ex. 7(a)

Becky B. Allenbach, Chief
Grants and Drinking Water Protection Branch
Water Protection Division - Region 4
404-562-9687

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Kenneth L. Mitchell, Ph.D. | Special Assistant to the Director |
Air, Pesticides, and Toxics Management Division
U.S. Environmental Protection Agency | 61 Forsyth Street, SW | Atlanta, GA 30303
Voice: 404-562-9065 | Fax: 404-562-9066 | Email: mitchell.ken@epa.gov

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Becky

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Grants and Drinking Water Protection Branch
Water Protection Division
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Sent: Tuesday, October 17, 2017 4:08 PM
To: Buckley, Timothy <Buckley.Timothy@epa.gov>; Strynar, Mark <Strynar.Mark@epa.gov>; Lindstrom, Andrew <Lindstrom.Andrew@epa.gov>; Allenbach, Becky <Allenbach.Becky@epa.gov>; Kemker, Carol <Kemker.Carol@epa.gov>; Mitchell, Ken <Mitchell.Ken@epa.gov>; Banister, Beverly <Banister.Beverly@epa.gov>; Jones, Aaryn <Jones.Aaryn@epa.gov>; France, Danny <France.Danny@epa.gov>
Cc: Scott, Michael <michael.scott@ncdenr.gov>; Woosley, Julie <julie.woosley@ncdenr.gov>; Johnson, Chris <chris.johnson@ncdenr.gov>; Cox, Heidi <heidi.cox@ncdenr.gov>; Allen, Trent <trent.allen@ncdenr.gov>; Gregson, Jim <jim.gregson@ncdenr.gov>; michael.abraczinskas@ncdenr.gov
Subject: FW: data requested

Forwarding air emissions data.

Linda Culpepper
Deputy Director
Division of Water Resources
North Carolina Department of Environmental Quality

1611 Mail Service Center
Phone: 919-707-9014

From: Abraczinskas, Michael
Sent: Tuesday, October 17, 2017 3:55 PM
To: Culpepper, Linda <linda.culpepper@ncdenr.gov>
Subject: data requested

Linda,
Attached you'll find the emissions data requested by EPA today. Please pass along to the points of contact.
Thanks!
-Mike

Mike Abraczinskas, EIT, CPM
Director, Division of Air Quality
North Carolina Department of Environmental Quality

919 707 8447 office
michael.abraczinskas@ncdenr.gov

217 West Jones Street
1641 Mail Service Center
Raleigh, NC 27699

<image001.png>

<DEQ Emissions Information Dimer Acid.docx>

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 2 1 2011

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

MEMORANDUM

SUBJECT: Request for Approval of a Consent Agreement and Proposed Final Order
In the Matter of: E.I. du Pont de Nemours and Company
Docket No. TSCA-HQ-2011-5052

FROM: Adam M. Kushner, Director
Office of Civil Enforcement

TO: Environmental Appeals Board

A. Introduction

Attached for your approval is the proposed Consent Agreement and Final Order (CAFO) to settle a civil penalty action against E.I. du Pont de Nemours and Company (Respondent or DuPont), for violations of section 15(2) of the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2614(2). Violations of TSCA section 15(2) are subject to penalties pursuant to section 16(a) of TSCA, 15 U.S.C. § 2615(a). This action is settled pursuant to 40 C.F.R. §§ 22.13(b) and 22.18, before the filing of a complaint. I have reviewed the CAFO and determined that it is consistent with TSCA and applicable United States Environmental Protection Agency (EPA) policies.

EPA determined that DuPont is not eligible for the *Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations*, 65 *Fed. Reg.* 19,618 (April 11, 2000) (Audit Policy) because DuPont failed to meet Condition 7 (No Repeat Violation) of the Audit Policy in that DuPont violated a TSCA section 5(e) Order on Consent.

B. Statement of the Facts

Respondent voluntarily disclosed to EPA on April 20, 2010, that four lots of a manufactured substance were not in compliance with requirements set forth in a TSCA section 5(e) consent order. Specifically, starting material used in the production of a substance exceeded numerical limits in the TSCA section 5(e) order. The name of the starting material has been declared confidential business information (CBI) by Respondent and will be referred to as Chemical A. Respondent used the non-compliant starting material in four separate lots on the following dates: November 9, 2009, December 12, 2009, January 24, 2010, and February 13, 2010.

EPA reviewed the substance manufactured by DuPont using the non-compliant starting material and has determined that, although the substance exceeded the requirements in the 5(e) order, the substance does not pose an unreasonable risk if distributed in commerce.

C. Summary of the Violations

TSCA section 15 states that "[i]t shall be unlawful for any person to– (1) fail or refuse to comply with . . . (C) any rule promulgated or order issued under section 2604 or 2505 of this title . . ." EPA alleges that Respondent failed to comply with TSCA section 15(1)(C) on four occasions by using the starting material with analytes that exceeded the limits of the TSCA section 5(e) order for Chemical A.

D. Application of the Penalty Policy

The proposed civil penalty of $52,500 is consistent with the penalty guidelines set forth in the *TSCA Section 5 Enforcement Response Policy* (TSCA ERP) (June 8, 1989) (copy attached).[1] The TSCA ERP provides guidance for penalty assessment based on the Agency's interpretation of the statutory factors for determining the amount of a TSCA civil penalty. Section 16(a)(2)(B) of TSCA, 15 U.S.C. § 2615(a)(2)(B), requires the Agency to consider "the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require."

1. Calculation of the Gravity-Based Penalty

Pursuant to the ERP, the proposed civil penalty is determined by calculating the gravity-based penalty (GBP) and considering adjustments to the GBP. The GBP was determined by considering the nature, circumstances, and extent of the violation:

Nature: Noncompliance with TSCA section 5(e) orders is designated as a "Chemical Control Violation" under the TSCA ERP. See page 7 of TSCA ERP.

Circumstances: The circumstance level (probability that harm will result from a particular violation) for a violation of a production ban or a restriction imposed by a TSCA section 5(e) consent order is designated as "Level 1 and per day." (See page 9 of the TSCA ERP.)

Extent: The extent level (potential harm) is designated as "major." Extent reflects the potential harm to EPA's hazard/risk assessment process or harm to human health or the environment. DuPont used the non-compliant starting material in a volume greater than 2,500 pounds for each lot, so the extent level is major. See the matrix on page 13 of the TSCA ERP.

[1] The policy can be found on the internet at the following address: http://www.epa.gov/compliance/resources/policies/civil/tsca/tscasec5erpamend-060889.pdf.

The gravity of the violation is determined by taking into account the nature, circumstances and extent of the violation. Since the statutory factor of "nature" is a constant throughout the ERP, and the statutory factor of "gravity" is a dependent variable, the GBP is determined by applying a matrix with "circumstances" on the vertical axis and "extent" along the horizontal axis.

Each day Respondent used the chemical substance that did not comply with the TSCA section 5(e) order is one violation. Respondent manufactured on four days resulting in four violations. Using the matrix value provided in the ERP for a level 1, major violation, the "base penalty" for these TSCA violations is $37,500 per violation.

4 x $37,500 = $150,000

The unadjusted **GBP is $150,000.**

2. Adjustments to Gravity-Based Penalty

Once the GBP has been determined, the Agency makes any upward or downward adjustments to the penalty amounts by taking into account the following factors with respect to the violator: degree of culpability, history of prior such violations, ability to pay, ability to continue in business and such other matters as justice may require (*e.g.*, voluntary disclosure of the violation). The document entitled *Guidelines for Assessment of Civil Penalties Under Section 16 of the Toxic Substances Control Act; PCB Penalty Policy*, 45 *Fed. Reg.* 59,770 (Sept. 10, 1980) (Guidelines) sets forth additional explanations for each of the adjustment factors discussed below.[2] The TSCA ERP states that it must be read in conjunction with the Guidelines. Therefore, the discussion below incorporates the criteria described in both the TSCA ERP and Guidelines.

Respondent voluntarily disclosed the four violations in writing on April 20, 2010. In that letter, Respondent requested consideration under the Audit Policy or the ERP. As discussed above, EPA has determined that Respondent does not meet the Audit Policy because it failed to meet Condition 7 (No Repeat Violation) of the Audit Policy in that Respondent violated a TSCA section 5(e) order on consent. However, Respondent is eligible for reductions under the ERP for a voluntary disclosure. According to the TSCA ERP at page17, "[v]oluntary disclosure of a violation will result in a 25% reduction of the penalty."

In the disclosure letter of April 20, 2010, Respondent stated that its disclosure was made within 21 days of determining that a violation had occurred. "An additional 25% reduction may be given to those companies which report the potential violation to EPA within 30 days of having reason to believe that they may be in violation." TSCA ERP page 17. In its letter, Respondent described the audit that lead to the discovery of the violation and the process it used to review the chemistry of the substances involved. The letter gives details of the results of

[2] The policy can be found on the internet at the following address: http://www.epa.gov/compliance/resources/policies/civil/tsca/tscapen.pdf

analysis and compares those results to the requirements of the TSCA section 5(e) order. Because Respondent self-disclosed the results of the audit within 30 days of determining a violation had occurred, Respondent's gravity-based penalty is reduced an additional 25%.

Respondent halted its use of the non-compliant products and quarantined all stocks immediately upon learning of the violation. The TSCA ERP at page 19 states, "[a] company would generally qualify for a downward adjustment if it immediately halts the violative activity, takes steps to rectify the situation and there is no finding of culpability." In its disclosure letter, Respondent sought EPA's determination for next steps. By halting its use of the non-compliant products and working with EPA on next steps, Respondent qualifies for the full fifteen (15%) reduction for attitude.

The total adjustment to the gravity-based penalty is sixty-five percent (65%). The resulting adjusted GBP is:

$150,000 - (150,000 X .65) = $52,500.

For the adjustment factors: degree of culpability, history of violations, ability to pay, and ability to continue in business, EPA determined Respondent's situation did not justify additional reductions or increases in the penalty. Respondent's behavior was neither willful nor did Respondent lack control over its ability to comply. Further, EPA concluded that Respondent is able to pay the penalty and continue in business without any downward adjustment.

The economic benefit for these violations is negligible and assumed to be captured in the gravity-based penalty. Therefore, the penalty was not adjusted upward to capture the economic benefit derived from the noncompliance. The final penalty for settlement purposes is **$52,500.**

FINAL SETTLEMENT PENALTY: $52,500

3. Human Health and Environmental Concerns Raised by Violations

Respondent's violation presented a potential harm to the Agency's TSCA section 5(e) program and potential harm to human health and environment. TSCA section 5(e) orders are important to assure potential hazards are addressed before a chemical is used commercially. By exceeding the limit in the order, DuPont's violations had the potential for a harmful impact on human health and the environment.

4. Disposition of Substances

The Consent Agreement contains conditions for the release of products that Respondent manufactured using Chemical A. There are no additional steps required to remedy Respondent's violations.

5. Past or Pending Actions

There are no past or pending actions involving the Respondent arising out of the same or similar facts.

6. The Public Interest is Served by the Agreement

The public interest is served by this Consent Agreement because it may deter future violations.

E. Recommendation

For the forgoing reasons, I recommend that you enter the proposed order. If you have any questions concerning this memorandum or the attached CAFO, please contact Mark Garvey, an attorney on my staff in the Office of Civil Enforcement at (202) 564-4168.

Attachments

BEFORE THE ENVIRONMENTAL APPEALS BOARD
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C.

In the Matter of:	)	
E.I. du Pont de Nemours and Company	)	Docket No. TSCA-HQ-2011-5052
Respondent	)	

CONSENT AGREEMENT

Complainant, United States Environmental Protection Agency (EPA or Agency), and Respondent, E.I. du Pont de Nemours and Company (DuPont) (collectively, the Parties), having consented to the entry of this Consent Agreement and proposed Final Order before the taking of any testimony and without adjudication of any issues of law or fact, consent to the terms of this Consent Agreement and attached Final Order.

I. PRELIMINARY STATEMENT

1. This civil administrative proceeding for the assessment of penalties pursuant to section 16(a) of the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2615(a), is being simultaneously commenced and concluded pursuant to 40 C.F.R. §§ 22.13(b) and 22.18(b)(2)-(3).

2. To avoid the disruption of orderly business activities and expense of protracted and costly litigation, Respondent, for purposes of this proceeding: (1) admits that EPA has jurisdiction

over the subject matter in this Consent Agreement; and, (2) consents to the terms of this Consent Agreement and Final Order.

3. The Respondent waives any defenses it might have as to jurisdiction.

II. EPA'S FINDINGS OF FACT AND LAW

COUNT I

4. Respondent is a corporation located at 1007 Market Street, Wilmington, Delaware 19898, incorporated in Delaware and is a "person" as defined in 40 C.F.R. § 720.3(x) and, as such, is subject to TSCA and its regulations.

5. Respondent manufactures, processes, or distributes in commerce the chemical substances or mixtures or in the past has manufactured, processed, or distributed in commerce the chemical substances or mixtures addressed in this Consent Agreement as those terms are defined in TSCA § 3, 15 U.S.C. § 2602.

6. TSCA § 5(e), 15 U.S.C. § 2604(e), provides that "(e) Regulation pending development of information (1)(A) If the Administrator determines that- (i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a) of this section; and (ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, or (II) such substance is or will be produced in substantial quantities and such substance either enters or may reasonably be

anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance, the Administrator may issue a proposed order, to take effect on the expiration of the notification period . . . to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance . . ."

7. In a letter dated April 20, 2010, Respondent voluntarily disclosed to EPA that four lots of starting material having an analyte "slightly over the [TSCA § 5(e)] Consent Order limit were used in the manufacture of Consent Order PMN substances." The starting material at issue has been declared Confidential Business Information by Respondent and will be referenced in this matter as Chemical A and its analyte.

8. Respondent manufactured four separate lots of Chemical A on November 9, 2009, December 12, 2009, January 24, 2010, and February 13, 2010 that failed to meet one of the analyte limit requirements in the TSCA § 5(e) Consent Order.

9. Respondent's use of the four lots of Chemical A during the manufacture of Consent Order PMN substances constitutes four violations under TSCA § 15(1)(C), 15 U.S.C. § 2614(1)(C).

10. Pursuant to section 15(1)(C) of TSCA, 15 U.S.C. § 2614 (1), "[i]t shall be unlawful for any person to— (1) fail or refuse to comply with . . .(C) any rule promulgated or order issued under section 2604 or 2605 of this title . . ."

11. Violations of section 15(1)(C) of TSCA subjects an entity to civil penalties pursuant to § 16(a) of TSCA, 15 U.S.C. § 2615(a).

III. CIVIL PENALTY

12. The proposed penalty in this matter is **$52,500**. The penalty is consistent with the *TSCA Section 5 Enforcement Response Policy*, issued August 5, 1988, as amended June 8, 1989 and July 1, 1993 (TSCA ERP). The TSCA ERP was developed in accordance with the *Guidelines for Assessment of Civil Penalties Under Section 16 of the Toxic Substances Control Act; PCB Penalty Policy*, which sets forth a general penalty assessment policy for TSCA violations. 45 Fed. Reg. 59,770 (Sept. 10, 1980) (Penalty Policy). The TSCA ERP establishes a framework for applying the statutory factors to be considered in assessing a civil penalty, *i.e.*: "the nature, circumstances, extent and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require." 15 U.S.C. § 2615(a)(2)(B).

13. The proposed civil penalty in this case reflects: (1) a determination of the Gravity-based Penalty (GBP); and, (2) adjustments to the GBP, taking into account the statutory factors.

14. Not more than thirty (30) calendar days after the effective date of the Final Order, respondent shall ***either***:

15. Dispatch a cashier's or certified check in the amount of **$52,500** made payable to the order of the "Treasurer of the United States of America," and bearing the case docket number TSCA HQ-2011-5052, to the following address:

U.S. Environmental Protection Agency
Fines and Penalties
Cincinnati Finance Center
PO Box 979077
St. Louis, MO 63197-9000

OR

16. Effect a wire transfer in the amount of **$52,500** with the notation "DuPont Civil Penalty Docket No. TSCA-2011-5052," by using the following instructions:

Federal Reserve Bank of New York
ABA = 021030004
Account = 68010727
SWIFT address = FRNYUS33
33 Liberty Street
New York, NY 10045

[Field Tag 4200 of the Fedwire message should read "D 68010727 Environmental Protection Agency."]

17. Respondent shall forward a copy of the check or documentation of a wire transfer to:

Tony R. Ellis, Case Development Officer
Waste and Chemical Enforcement Division (2249A)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW (Room No. 5041-A)
Washington, DC 20460
(202) 564-4167
Ellis.Tony@epa.gov

18. If Respondent fails to pay the civil penalty of **$52,500** within thirty (30) calendar days of the execution of the Final Order, then Respondent shall pay an additional stipulated penalty of $1,000 per calendar day, plus interest, as provided for in 31 U.S.C. § 3717, as in effect on the date of execution of the Final Order, unless Complainant in writing excuses or mitigates the stipulated penalty. Complainant may excuse or mitigate the stipulated penalty if Complainant determines in its sole discretion, that failure to comply occurred despite Respondent's exercise of good faith and due diligence. If additional stipulated penalties are due, Complainant will dispatch to Respondent a demand letter specifying the total amount due and owed by Respondent, including any interest allowed by law. Within fourteen (14) calendar days following Respondent's receipt of such demand letter, Respondent shall pay

the stipulated penalty in the manner specified in this section.

IV. Reservation of Rights and Covenant Not to Sue

19. Payment of the penalty resolves the civil administrative claims alleged in this Consent Agreement provided that Respondent distributes, within one year of the Final Order for this Consent Agreement, all quarantined stocks of products made with Chemical A exceeding the TSCA §5(e) Consent Order limit of its analyte and identified in Respondent's April 10, 2010 letter to EPA. These products do not pose an unreasonable risk.

20. Pursuant to 40 C.F.R. § 22.18(b)(2), Respondent waives its right to contest the allegations herein, its right to appeal the Final Order and its right to request a judicial or administrative hearing on any issue of law or fact set forth in, and resolved by, this Consent Agreement.

21. For the sole purpose of establishing Respondent's compliance history in any future enforcement proceeding that EPA may bring against Respondent within five (5) years of the date of the execution of the Final Order, Respondent agrees not to challenge the violations alleged in this Consent Agreement. Otherwise, Respondent neither admits nor denies the allegations, but consents to the terms and conditions of this Consent Agreement and Final Order.

22. By executing this Consent Agreement, Respondent certifies that regarding the violations alleged herein, Respondent is in compliance with §§ 5 and 15(1)(C) of TSCA; 15 U.S.C. §§ 2604 and 2614(1)(C) except for the quarantined stocks discussed in paragraph 19.

23. This settlement is conditioned upon the thoroughness and accuracy of Respondent's submissions to EPA in this matter.

24. Compliance with this Consent Agreement and Final Order shall not be a defense to any subsequent action EPA may commence pursuant to federal law or regulation for violations occurring after the date of this Consent Agreement, or any violations of TSCA not alleged in this Consent Agreement that may have occurred prior to the date that this Consent Agreement is fully executed by both Parties.

25. Nothing in this Consent Agreement or the Final Order is intended, nor shall be construed, to operate in any way to resolve any criminal liability of Respondent.

V. OTHER MATTERS

26. This Consent Agreement shall be binding upon the Parties, and their respective officers, directors, employees, successors and assigns. The undersigned representative of each Party certifies that he or she is duly authorized by his or her respective Party to sign this Consent Agreement.

27. This Consent Agreement shall take full effect upon signing and filing of the Final Order by EPA's Environmental Appeals Board.

28. Respondent's obligations under this Consent Agreement shall end when it has paid in full the scheduled civil penalty, paid any stipulated penalties, distributed quarantined stocks in a timely manner, and submitted documentation required by the Consent Agreement and Final Order.

29. All of the terms and conditions of this Consent Agreement together comprise one settlement agreement, and each of the terms and conditions is in consideration for all of the other terms

and conditions. This Consent Agreement shall be null and void if any term or condition of this Consent Agreement is held invalid or is not executed by all of the signatory parties in identical form, or is not approved in such identical form by the EPA Environmental Appeals Board.

30. The penalty, including any stipulated penalties specified above, represents civil penalties assessed by EPA, and shall not be deductible for purposes of federal taxes.

31. Failure of Respondent to remit the civil penalties provided herein will result in this matter being forwarded to the United States Department of Justice for collection.

32. The Parties agree to bear their own costs and attorneys fees.

WE AGREE TO THIS:

Rosemarie A. Kelley, Director
Office of Civil Enforcement
Office of Enforcement and Compliance Assurance
United States Environmental Protection Agency

Date: Sep. 6, 2011

John W. Moriarty
Global Business and Market Director
E.I du Pont de Nemours Company

Date: 7/10/11

Mark Garvey, Attorney
Waste and Chemical Enforcement Division
Office of Civil Enforcement
Office of Enforcement and Compliance Assurance
United States Environmental Protection Agency

Date: 8/16/11

Andrea Malinowski, Attorney
Corporate Counsel
DuPont Legal

Date: 12 July 2011

BEFORE THE ENVIRONMENTAL APPEALS BOARD
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C.

In the Matter of:	)	
E.I. du Pont de Nemours and Company	)	Docket No. TSCA-HQ-2011-5052
Respondent	)	

FINAL ORDER

Pursuant to Section 16 of the Toxic Substance Control Act (TSCA), 15 U.S.C. § 2615, Complainant, United States Environmental Protection Agency (EPA or Agency), and Respondent, E.I. du Pont de Nemours and Company (DuPont) (collectively, the Parties), having signed and consented to entry of the attached Consent Agreement incorporated by reference into this Final Order,

IT IS ORDERED THAT:

1. Respondent, DuPont, shall comply with all terms of the Consent Agreement;

2. Respondent is assessed a civil penalty of **$52,500.** (Fifty-two thousand, five hundred dollars).

3. Respondent shall, within thirty (30) days of the effective date of this Order, in accordance with the payment provisions set forth in the Consent Agreement, via a certified or cashier's check or through a wire transfer make payment of $52,500 as described in the Consent Agreement.

IT IS SO ORDERED.

By: _____
Environmental Appeals Board

Dated: _____

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing Final Order in the Matter of: E.I. du Pont de Nemours and Company, Docket No. TSCA-HQ-2011-5052, were sent to the following persons in the manner indicated:

By Facsimile and Pouch Mail:

Mark Garvey, Esq.
Waste and Chemical Enforcement Division (Mail Code 2249A)
Office of Civil Enforcement
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
(202) 564-4168
Fax No. (202) 564-0035

By First Class U.S. Mail:

Andrea Malinowski, Attorney
Corporate Counsel
DuPont Legal
1007 Market Street
Wilmington, DE 19898

Annette Duncan, Secretary
Environmental Appeals Board (Mail Code 1103B)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460-0001

To: Miles, James[miles.james@epa.gov]; Saenz, Diana[Saenz.Diana@epa.gov]
From: Sullivan, Greg
Sent: Fri 6/1/2018 2:40:58 PM
Subject: FW: Notice of Intent - TSCA citizen suit
canond5705d.enrd.doj.gov_Exchange_05-29-2018_11-34-28.pdf
ATT00001.htm

James and Diana – I'd like to provide RAK with an update and next steps. Can you take a look and add/edit as needed. I'd like to send today before I call the region back.

Rosemarie,

FYI - We met with WED yesterday. Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5

Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5

Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5

From: Palmer, Leif
Sent: Tuesday, May 29, 2018 2:16 PM
To: Kelley, Rosemarie <Kelley.Rosemarie@epa.gov>
Cc: Rubini, Suzanne <Rubini.Suzanne@epa.gov>; Sullivan, Greg <Sullivan.Greg@epa.gov>
Subject: Fwd: Notice of Intent - TSCA citizen suit

Hi — our internet is out. Please see the email from DOJ. Greg, I left you a voicemail about this.

Sent from my iPhone
Begin forwarded message:

> **From:** "Mann, Martha (ENRD)" <Martha.Mann@usdoj.gov>
> **Date:** May 29, 2018 at 11:54:34 AM EDT
> **To:** "palmer.leif@epa.gov" <palmer.leif@epa.gov>, "Grant.Brian@epa.gov" <Grant.Brian@epa.gov>
> **Cc:** "Cirino, Paul (ENRD)" <Paul.Cirino@usdoj.gov>
> **Subject: Notice of Intent - TSCA citizen suit**
>
> Hello Leif and Brian,
>
> Just checking in to see if you are aware of the attached notice of intent, and whether you have assigned the matter to an attorney in your office.

Thanks so much,
Martha

Martha C. Mann
United States Department of Justice
Environment and Natural Resources Division
202.514.2664

TOXIC SUBSTANCES CONTROL ACT – NEW AND EXISTING CHEMICALS PROGRAM

COMPLIANCE MONITORING INSPECTION REPORT

The Chemours Company

Fayetteville Works
22828 NC Highway 87 West
Fayetteville, NC 28306-7332

Report Date: April 24, 2018

Report Prepared By:
Verne George
U.S. Environmental Protection Agency, Region 4
Chemical Management and Emergency Planning Section
61 Forsyth Street, SW
Atlanta, GA 30303

Inspectors:

Verne George	EPA Region 4, Lead Inspector
Keith Bates	EPA Region 4
Daryl Hudson	Eastern Research Group, Contractor to the EPA
Dan-Tam Nguyen	Eastern Research Group, Contractor to the EPA

Inspection Dates: June 28 - 29, 2017

INFORMATION REDACTED (BLACKED OUT) IN THIS REPORT IS INFORMATION PROVIDED TO THE EPA REGION 4 BY THE FACILITY WITH A TSCA CBI CLAIM PURSUANT TO TSCA SECTION 14(C), REQUEST FOR NONDISCLOSURE

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PPVE Process Area

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P-95-0980)

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4.2. Report – Co-Authors

4.3. Report – Technical Reviewer

4.4. Report - Approver

EXHIBITS

Section A - Inspection Documents

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A3 TSCA Inspection Confidentiality Notice (EPA Form 7740-4)
A4 TSCA Receipt for Samples and Documents (EPA Form 7740-1)
A5 Document No. 0101F1908562817: Site Map
A6 Document No. 0201F1908562817: Presentation, Fayetteville Works Overview
A7 Document No. 0301F1908562817: PPVE Flow Chart
A8 Document No. 0401F1908562817: EPA Consent Order Modification Letter, February 1, 2010
A9 Document No. 0501F1908562817: Safety Data Sheet – GX902
A10 Document No. 0601F1908562817: Safety Data Sheet – GX905C
A11 Document No. 0701F1908562817: Safety Data Sheet – GX905D
A12 Document No. 0801F1908562817: Safety Data Sheet – GX903
A13 Document No. 0901F1908562817: Copies of Product Labels (GX905D, GX902, GX903)
A14 Document No. 1001F1908562817: Export Notices

Section B - Supporting Documents (provided after the inspection)

B1 DuPont/Chemours Notice of Transfer Document
B2 [redacted]
B3 PPVE Process Narrative
B4 Chemours September 1, 2017, letter to the EPA
B5 Chemours letter to the EPA with analytical data
B6 [redacted]
B7 [redacted]
B8 [redacted]
B9 [redacted]
B10 GenX Customer List
B11 [redacted]
B12 [redacted]
B13 DuPont December 10, 2010, Letter
B14 DuPont April 27, 2011, Letter
B15 EPA August 1, 2011, Letter
B16 Chemours Permeation Testing
B17 DuPont August 20, 2009, Letter
B18 EPA February 1, 2010, Modification of Order
B19 Chemours August 19, 2017, Letter
B20 2016 Amended CDR

B21 Flow Diagram and Production day/volume
B22 Air Emission Data
B23 Chemours September 6, 2017, Letter
B24 Chemours September 1, 2017, Letter
B25 Chemours October 13, 2017, Letter
B26 Chemours July 31, 2017, Letter
B27 TSCA Certified Statement
B28 2016 Original CDR and Amended CDR
B29 2016 Original CDR and Amended CDR
B30 2016 Original CDR and Amended CDR
B31 EPA August 15, 2017 IRL
B32 Chemours August 22, 2017, Letter
B33 Chemours July 31, 2017, Letter
B34 Chemours October 4, 2017, Letter
B35 PPVE Block Flow Diagram
B36 P&ID # W553421
B37 [redacted]
B38 HFPO Block Flow Diagram
B39 September 6, 2017 Letter
B40 [redacted]
B41 March 29, 2018 Letter
B42 Air Emission Data
B43 [redacted]
B44 Vinyl Ether South P&ID
B45 [redacted]
B46 February 2, 2018 Letter

ACRONYMS

[redacted]

ADME	Absorption, Distribution, Metabolism, Excretion
[redacted]	
APF	Applied Protective Factor
APFO	Ammonium perfluorooctanoate
ASE	Accelerated Solvent Extraction
CASRN	Chemical Abstracts Service Registration Number
CBI	Confidential Business Information
CDR	Chemical Data Reporting
[redacted]	
DCO	Document Control Officer
EPA	U.S. Environmental Protection Agency
ERG	Eastern Research Group, Inc., Contractors to the EPA
[redacted]	
LLC	Limited Liability Company
NCEL	New Chemical Exposure Limits
NCDEQ	North Carolina Department of Environmental Quality
NOC	Notice of Commencement
OCSPP	EPA's Office of Chemical Safety and Pollution Prevention
P&ID	Piping and Instrumentation Diagram
[redacted]	
PAIR	Preliminary Assessment Information Rule
PBT	Persist in the environment/could bio-accumulate/toxic to people, wild mammals, & birds
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctane sulfonate
[redacted] Perfluorethoxypropionylfluorid [redacted]	
PMN	Premanufacture Notice
[redacted]	
PPVE	Perfluoropropyl vinyl ether
[redacted]	
SNUN	Significant New Use Notice
SNUR	Significant New Use Rule
TSCA	Toxic Substances Control Act
WWTP	Waste Water Treatment Plant

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SUMMARY

The Chemours Company FC, LLC (Chemours) is a chemical manufacturer, processor and exporter as defined under the Toxic Substances Control Act (TSCA). On June 28 - 29, 2017, a TSCA compliance monitoring inspection was conducted by the U.S. Environmental Protection Agency at the Chemours' Fayetteville Works Facility located at 22828 NC Highway 87 West, Fayetteville, North Carolina (the Facility). The inspection was conducted due to community concerns with the reported release of potentially harmful chemicals, associated with Chemours' GenX process, into the Cape Fear River, a source of drinking water supply for numerous counties in North Carolina.

Chemours represents that GenX is a technology developed by E. I. du Pont de Nemours and Company (DuPont) and now used by Chemours to manufacture high-performance fluoropolymers without the use of perfluorooctanoic acid (PFOA). The GenX technology is used at the Facility in the [redacted]

[redacted]

Based on oral and written statements provided by Chemours, during the production of PPVE [redacted]

During the inspection, Chemours stated that after June 21, 2017, the Facility began collecting the aqueous waste generated in the wet scrubber and storing it in temporary storage tanks. The Facility then ultimately ships the waste to an offsite facility for incineration rather than directing it to the WWTP which was discharged to the Cape Fear River. [redacted] (Section 2.4.2) of this report.

Based on inspection observations and the review of records provided by Chemours, the Facility: (1) manufactured, processed, exported and/or distributed in commerce, several chemical substances subject to TSCA; [redacted]

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SCOPE

The scope of this inspection includes a review of Chemours' compliance with TSCA Sections 4, 5, 8, 12 and 13 which covers activities that occurred at the Facility on or before June 29, 2017, (the final date of the inspection). Between June 29, 2017, and March 14, 2018, the EPA submitted several follow up information request letters to Chemours. Between July 1, 2017, and March 29, 2018, Chemours responded to the EPA's information request letters.

In addition to documenting facts and observations based on the inspection and information provided by Chemours, some preliminary evaluation of compliance with TSCA is included in this inspection report.

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1. INTRODUCTION

In June 2017, in response to the community's concerns about the reported release of potentially harmful chemicals (GX902 and GX903) into the Cape Fear River by Chemours' Fayetteville Works Facility, North Carolina (the Facility), the U.S. Environmental Protection Agency commenced a Toxic Substances Control Act (TSCA) investigation. The chemicals of concern were associated with the GenX technology developed by E. I. du Pont de Nemours and Company (DuPont). The GenX technology is now used by Chemours to manufacture high-performance fluoropolymers without the use of Perfluorooctanoic acid (PFOA). Based on this information, the EPA immediately began investigating these concerns.

[redacted] the EPA received two TSCA Premanufacture Notices (PMNs) from DuPont. The notices were submitted pursuant to TSCA Section 5. The PMN number [redacted] was assigned to the chemical substance with the generic chemical identity, perfluorinated aliphatic carboxylic acid (Chemical Abstracts Service Registration Number [redacted] and PMN number [redacted] was assigned to the chemical substance with the generic chemical identity, [redacted]. In the PMNs, DuPont claimed the specific chemical identities and the CASRNs of the chemical substances as TSCA Confidential Business Information (CBI). This claim was not made in later documents submitted to the EPA by Chemours.

[redacted], the EPA and DuPont entered into a final TSCA Section 5(e) Consent Order (the Consent Order) governing the manufacture, processing, use, distribution in commerce, release and disposal of the PMN substances [redacted] Section V of the Consent Order includes, the following conclusions: [redacted].

The Consent Order indicates that the EPA concerns were based on data collected on the PMN substances, analogous to other similar chemicals, and to PFOA [redacted] which were both under review by EPA for similar PBT concerns. PFOA and its salt, Ammonium perfluorooctanoate (APFO), are long-chain synthetic perfluorinated chemicals (C8), which have human health and environmental concerns, and have been used in the manufacture of products such as Teflon®. Due to the possibility or likelihood of the use as a major substitute for PFOA, the EPA states in the Consent Order, "more information is needed on the toxicity and pharmacokinetics of the PMN substance [redacted] that will be applied to the characterization of both PMN substances" and also noted the "high concern for possible environmental effects over the long-term."

Due to the stated concerns of the EPA, the Consent Order authorized the manufacture of the PMN substances, but under the terms in Section II (Control of Effluent and Emissions), the EPA noted that DuPont "shall recover and capture (destroy) or recycle the PMN substances at an overall efficiency of 99% from all effluent process streams and air emissions (point source and fugitive)."

Pursuant to Section V of the Consent Order, (Successor Liability Upon Transfer of Consent Order), a "Successor in Interest" means a person outside the Company who has acquired the Company's full interest in the rights to manufacture the PMN substances, including all ownership rights and legal liabilities, through a transfer document signed by the Company, as transferor, and the Successor in Interest, as transferee. According to the Transfer Notice submitted to the EPA by Chemours, the effective date of the transfer of the manufacture rights and interest for the chemicals subject to the Consent Order was February 1, 2015, (See Exhibit B1 – DuPont/Chemours Notice of Transfer Document).

2. INSPECTION

2.1. Inspection Notice

To determine Chemours' compliance with the Consent Order for the PMN substances and with other requirements of TSCA, the EPA determined that an on-site TSCA compliance monitoring inspection was warranted. An inspection team was organized and included Verne George, EPA Region 4 lead TSCA inspector and Keith Bates, EPA Region 4 TSCA Co-inspector, with expertise in addressing confidentiality of TSCA CBI claims. The TSCA inspection team also included Daryl Hudson and Dan-Tam Nguyen, (experts in chemical processes and manufacturing) from Eastern Research Group, Inc. (ERG), contractors to the EPA with EPA TSCA inspection credentials.

On June 22, 2017, Verne George contacted Mr. Michael Johnson, Environmental Manager, for the Chemours operations at the Facility and former employee of DuPont to schedule a "for cause TSCA compliance monitoring inspection" to determine Chemours' compliance with TSCA Sections 4, 5, 8, 12, and 13. Based on the discussions with Mr. Johnson, the inspection was scheduled for June 28 - 29, 2017.

On June 22, 2017, the EPA Region 4, Chemical Management and Emergency Planning Section mailed an inspection notice (letter) to Chemours confirming the inspection date and requesting certain identified records be made available for review during the inspection. A copy of the letter was also emailed to Mr. Johnson on June 22, 2017, (See Exhibit A1 – Notice of Inspection Letter).

2.2. Inspection Entry

The final inspection team included all the planned inspection team members as follows:

Verne George	TSCA Lead Inspector (EPA Region 4)
Keith Bates	TSCA Co-inspector/TSCA CBI Document Control Officer (DCO) (EPA Region 4)
Daryl Hudson	TSCA Co-inspector (ERG)
Dan-Tam Nguyen	TSCA Co-inspector (ERG)

On June 28, 2017, the inspection team arrived at the facility security office at approximately 8:50 am. The security office called Mr. Johnson who shortly arrived at the security office to guide the inspection team to the main office building. Mr. Bates collected a small map of the Facility at the security office from a stack of such maps in plain view and available for site visitors after asking permission from the security guard (See Exhibit A5 - Document Number: 0101F1908562817: Site Map).

Upon arrival at the main office building, the inspection team signed in and was provided facility identity badges. The inspection team was escorted to a conference room and as the first step of the opening

conference each inspection team member presented their EPA credentials to the following Chemours representatives:

Ellis McGaughy	Fayetteville Works Manager;
Laura Korte	Global Product Manager;
Michael Johnson	Fayetteville Works Environmental Manager; and
Joel Blake	Fayetteville Works Environmental Health & Safety Manager.

Mr. George informed Chemours that the inspection was being conducted pursuant to TSCA Section 11 to determine compliance with TSCA Sections 4, 5, 8, 12, and 13. Mr. Johnson signed a TSCA Notice of Inspection (Form 7740-3) and Confidentiality Notice (Form 7740-4). The original copies were given to Chemours and a copy of each form was provided to the EPA (See Exhibit A2 – Notice of Inspection Form and Exhibit A3 – TSCA Inspection Confidentiality Notice).

Mr. George explained that the inspection would consist of: an opening conference with facility staff about the company, the nature of the company's business, chemical imports/exports and production processes; a tour of the facility; a private discussion and review of information provided by the facility that would only include the EPA representatives; and a closing conference with the Chemours representatives.

Mr. Bates explained the TSCA Inspection Confidentiality Notice and indicated that to ensure confidentiality of documents provided by the Facility, the Facility must make a TSCA CBI claim as documents are provided. Mr. Bates also indicated that no documents claimed by the Facility to contain TSCA CBI would be taken with the inspectors at the conclusion of the inspection. However, any such documents needed by the inspectors must be sent to his attention by mail after the inspection in an inner envelope marked "TSCA CBI – To Be Opened By Addressee Only," and an outer envelope with the EPA Region 4 mailing address. The facility was also directed to mail, in the same manner, copies of the documents to the ERG contractor's TSCA CBI Document Control Officer (DCO) at the ERG address provided.

2.3. Opening Conference

2.3.1. Introduction

Included in Section 2.3.2. of this report is a summary of the opening conference. Compliance evaluation is generally determined by the review of appropriate records provided by the facility. Details of the review of the information provided to the inspection team at the time of the inspection, and information provided by Chemours after the inspection, are discussed in Section 3.0 of this report.

2.3.2. Summary

An overview of information about the Facility was provided by Mr. Johnson in a slide show presentation. A hard copy of the slide show presentation was provided to the inspection team (See Exhibit A6 - Document Number: 0201F1908562817: Presentation, Fayetteville Works Overview). The summary indicated that Chemours owns the entire Facility. DuPont and Kuraray America, Inc., also operate at the Facility and all share the utilities, roads, grounds and emergency response responsibilities.

- The Facility was constructed by DuPont between 1968 and 1971. Production began in May 1970.

- The Facility consists of approximately 2,150 acres with approximately 400 acres within the fence line and is situated along the Cape Fear River.

- Chemours was a wholly owned subsidiary of DuPont when it acquired the Facility from DuPont on February 1, 2015. Chemours later spun off from DuPont on July 1, 2015.

- Chemours operates the following manufacturing areas at the Facility: (1) Nafion® IXM; (2) Polymer Processing Aid; (3) Monomers; and (4) Power/Utilities/WWTP.).

In the opening conference, Mr. Johnson indicated that the GenX technology is used in the [redacted] process at the Facility and that the [redacted] produces the chemical substances covered under the Consent Order [redacted]. Based on information provided by Chemours, the end products from the [redacted] include various concentrations of [redacted]. These products are identified by Chemours as GX902, GX903, GX905C and GX905D. Further description of these chemical substances can be found in Section 3.0 of this report.

Mr. Johnson asserted that the chemicals from the [redacted] covered in the Consent Order are not released into the Cape Fear River and that all of the waste generated from the [redacted] is trucked to an offsite disposal facility. Mr. Johnson indicated that some of the [redacted]. He also stated that dependent upon various conditions such as the pH level in the outfall, the chemical, GX903 [redacted] can form in the river. This CASRN [redacted]) is the same CASRN as the chemical that EPA assigned PMN number [redacted]. Mr. Johnson indicated that the Consent Order applies to the [redacted] and not the PPVE process, but due to the community concerns, beginning June 21, 2017, waste from the PPVE process has been collected in temporary storage tanks and will ultimately be shipped for incineration at an offsite facility when a contract is finalized.

The production managers for [redacted] discussed the processes during the opening conference. Summary flow charts for both the [redacted] and PPVE were provided to the inspection team, a TSCA CBI claim was made for the [redacted], but not for the PPVE flow chart.(See Exhibit A7 - Document No. 0301F1908562817: PPVE Flow Chart). All the copies of the summary flow chart for the [redacted] were returned to Mr. Johnson after the discussion due to Chemours' TSCA CBI claim on the process. To ensure that the inspection team fully understood the processes, both production managers were asked to create written summaries of the [redacted] and PPVE processes. The summaries were sent to the EPA and ERG after the inspection.

During the discussion of worker protection requirements required under the Consent Order, Chemours provided documentation that modifications to the Consent Order, as requested by DuPont, were approved by the EPA on February 1, 2010 (See Exhibit A8 - Document No. 0401F1908562817: EPA Consent Order Modification Letter, February 1, 2010).

2.4. Facility Tour

2.4.1. Introduction

As requested, Chemours gave the inspection team a tour of the Facility. The tour mainly focused on the [redacted] and PPVE processes. Chemours provided the EPA inspectors with fire resistant jump-suits and rubber gloves. The inspectors used their own hard hats, safety shoes, safety glasses and hearing

protection. The inspection team requested the tour to gain a general perspective and knowledge of the production areas to facilitate later review of summary flow charts, process diagrams and other operations information.

2.4.2. Summary

PPVE Process Area

The first area toured during the inspection was the PPVE process area. This area is described as the Nafion® IXM Monomers area and is the location of the Facility waste water treatment plant (WWTP). This area is on the east side of the Facility and is approximately 2,000 feet from the Cape Fear River. The land between the PPVE process area and the river is mostly wooded.

For the PPVE process, Chemours did not provide any information on releases of GX902 or GX903. Chemours did provide the following information indicating: (1) [redacted]; and (2) the [redacted]. Assuming all the [redacted] is converted to GX903 or GX902 and is incinerated at the same efficiency as provided for the [redacted] waste streams, the percentage released is [redacted]. There was not enough information provided to the inspection team to calculate the [redacted] in/out of the [redacted]. Chemours also indicated that as of June 21, 2017, KOH scrubber wastes are no longer being sent to the WWTP (collected and incinerated/deep well injected).

[redacted] Process Area

The next area toured during the inspection was the [redacted] area. [redacted]. Based on the [redacted] Flow Diagram and [redacted] Process Summary, Exhibits B11 and B12, [redacted]

The information provided by Chemours during and subsequent to the inspection indicates that the estimated annual air releases from the [redacted] are less than [redacted] percent. Chemours released approximately [redacted] from the [redacted] process. Based on Chemours batch sizes, batches/year, and annual production volume estimates, the percentage released is calculated to be approximately [redacted] percent. For details on the [redacted] estimate emissions, see Exhibit B42 - Air Emission Data.

2.5. Closing Conference

The inspection team concluded the first inspection day, June 28, 2017, at approximately 3:30 pm and scheduled the closing conference for the next day. The inspection team arrived at the main office building at approximately 9:00 am on June 29, 2017. Mr. Johnson assisted the inspection team in obtaining facility badges and escorted the team to the conference room. The inspection team held an

inspection team only private meeting at the beginning of the second inspection day to discuss topics needing clarification.

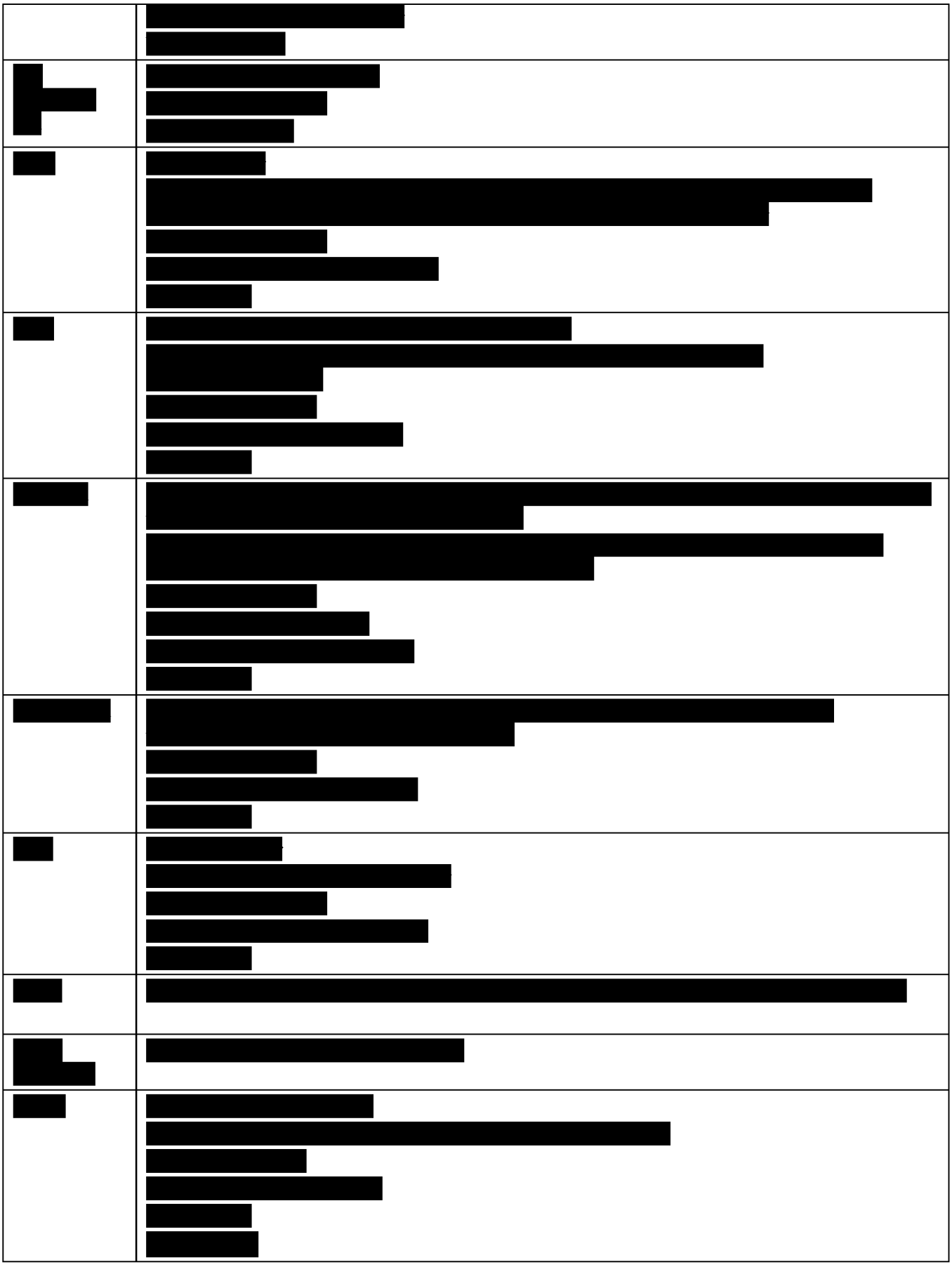
The closing conference began with a discussion of the topics needing clarification. The inspection team provided Chemours with a list of information that would need to be sent to the EPA and ERG after the inspection. A TSCA Receipt for Samples and Documents, EPA Form 7740-1 (See Exhibit A4 – TSCA Receipt for Samples and Documents) was created for the documents the inspection team collected during the inspection. Lastly, the inspection team discussed the EPA and ERG next steps which would be a review of the information provided by Chemours and potential requests for further information. The inspection concluded at approximately 12:30 pm.

3. FINDINGS

3.1. Introduction

The findings discussed below are based on statements and observations made during the inspection and on information provided by Chemours after the inspection.

For consistency and clarity, chemical substances referenced in this report will be referred to as follows from this point forward regardless of how the chemical substances are referred to in referenced documents and diagrams, unless otherwise identified:



[redacted]	[redacted] Propanoyl fluoride,2,3,3,3-tetrafluoro-2-[1,1,2,3,3,3-hexafluoro-2-(1,1,2,2,3,3,3-heptafluoropropoxy)propoxy]- [redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	Perfluorethoxypropionylfluorid [redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
PPVE	Perfluoropropyl vinyl ether Systematic Name: Propane, 1,1,1,2,2,3,3-heptafluoro-3-[(1,2,2-trifluoroethenyl)oxy]- CASRN: 1623-05-8 Molecular Formula: C5F10O PMN: None
[redacted]	[redacted]

	[redacted]

3.2. TSCA Section 4 Evaluation

Based on Chemours' raw material lists for 2015 and 2016, Chemours purchased [redacted] from a domestic supplier. The chemical substance was once subject to a [redacted]. The [redacted] Chemical was used at the Facility in the production of [redacted]. The chemical was sent offsite for incineration as part of the material collected in the waste fluorocarbon system.

3.3. TSCA Section 5 Evaluation

3.3.1. PPVE Process

3.3.1.1. PPVE Process Discussion

[redacted], DuPont and later Chemours in 2015, manufactured PPVE and [redacted] for commercial use. PPVE and [redacted] are manufactured in the PPVE process. Based on the intended use, PPVE and [redacted] are subject to TSCA. The PPVE production process involves the following steps: [redacted]. For a detail description of the production of PPVE and [redacted], see: (1) Section *3.4.5.2 of this report ([redacted] Discussion);* (2) Exhibit B3 - PPVE Process Narrative); (3) Exhibit A7 -PPVE Flow Chart; and (4) Exhibit B2 - [redacted].

During the inspection, Chemours provided a flow chart of the PPVE process. The PPVE Flow Chart indicates that either [redacted] or [redacted] may be present in the NPDES effluent discharged into the Cape Fear River depending on the pH level of the final effluent to outfall 002. For details on the release of [redacted] or [redacted] as discussed during the inspection, see Exhibit A7 - PPVE Flow Chart.

During the inspection, the inspection team requested a written detail summary of the PPVE process. On July 31, 2017, Chemours submitted to Region 4 and ERG a written summary of the PPVE process (See Exhibit: B3 - PPVE Process Narrative). The PPVE Process Narrative stated [redacted]

Based on the PPVE Process Narrative, [redacted]

[redacted].

According to statements made by Mr. Johnson during the inspection, the PPVE process and its waste streams are not regulated by the Consent Order for the chemical substances manufactured or processed for commercial purposes in the PPVE process.

3.3.1.2. PPVE Process Waste Stream

Based on Chemours' July 31, 2017, PPVE Process Narrative, [redacted]

In an effort to determine when Chemours first became aware of the release/forming of the GenX chemicals [redacted] in the WWTP or Cape Fear River, on August 15, 2017, Region 4 submitted a letter to Chemours regarding a description of the PPVE process. Region 4's request was as follows: "Regarding the PPVE process, when (date) did Chemours become aware that the GenX chemicals were being released to the Cape Fear River or formed in the Cape Fear River? For the period prior to the TSCA Inspection, if Chemours has analytic data/sample results of: (A) the earliest signs of [redacted] contamination in the PPVE sumps; or (B) earliest releases/forming of GenX chemicals in the Cape Fear River, please submit those records to the EPA."

On September 1, 2017, Chemours indicated [redacted] Chemours did not provide a direct response concerning the date/time period as to when they first became aware that [redacted] and/or [redacted] was released into the Cape Fear River or formed in the Cape Fear River. However, during the June 15, 2017, public meeting between Chemours and North Carolina local and state officials, Chemours indicated that DuPont was aware since 1980 that GenX was released into the Cape Fear River as a byproduct.

Chemours also provided analytic data for the time period covering June 14, 2017, and July 28, 2017 (See Exhibit B5 - Chemours letter to the EPA with analytical data).

During the inspection, the PPVE Flow Chart did not indicate that [redacted] was a component in the effluent that was released from Chemours WWTP to outfall 002. The PPVE Process Narrative provided by Chemours after the inspection indicated that [redacted] aeration [redacted]. For details on the formation and releases of the [redacted], see Exhibit B3 - PPVE Process Narrative. According to

Chemours, as discussed during the inspection, the PPVE process and its waste stream are not subject to the Consent Order.

For the PPVE process, Chemours did not provide any information on releases of [redacted]. Chemours did provide the following information: (1) [redacted] was sent to the waste fluorocarbon system (incineration) in 2016; and (2) the [redacted]

[redacted] efficient in removing [redacted] (based on stack testing). Assuming all the [redacted] is converted to [redacted] and is incinerated at the same efficiency as provided for the [redacted] waste streams, the percent released is [redacted] percent. Sufficient information is not available for the inspection team to calculate the [redacted] in/out of the [redacted]. Chemours also indicated that KOH scrubber wastes are no longer being sent to the WWTP (collected and incinerated/deep well injected).

Based on the information (records/discussions) provided by Chemours, there is no indication that Chemours informed the EPA of the PPVE process, as it relates to the presence of [redacted] and [redacted] in the effluent leaving the WWTP and the formation of [redacted] in the combined effluent going to outfall 002 which was ultimately discharged into the Cape Fear River.

Based on the PPVE Process Narrative, prior to June 21, 2017, [redacted]. The PPVE Process Narrative did not indicate how much or what percent of the waste was captured. (See Exhibit B3 - PPVE Process Narrative).

3.3.2. [redacted] Process

3.3.2.1. PMN, Issuance of Order and Notice of Commencement

On or about [redacted], DuPont submitted a consolidated PMN to the EPA for the manufacture of [redacted]. The EPA identified the PMNs as [redacted] respectively. Based on the information provided by Chemours, GenX is the technology used to identify the production process of the GenX chemicals. The GenX chemicals (PMN Substances) are manufactured in the [redacted] Process.

Based on the PMNs, the intended uses for the [redacted].

In addition, the intended uses for [redacted]

As referenced in the Preamble to the Consent Order (Preamble, Section V, EPA's Conclusions of Law), the following finding constitute the basis for the Consent Order: [redacted]. (See Exhibit B7- Consent Order, Section I).

The chemical substances [redacted] that are subject to the Consent Order are the same two chemical substances that are associated with the [redacted] process waste stream that were

either: (1) formed in the [redacted]; (2) formed in the [redacted]; or (3) formed in the Cape Fear River. During the PMN review period and during the negotiation of the Consent Order, Chemours did not provide any information to the EPA concerning: (1) the effluent (wastewater) from the PPVE process that contained some [redacted]; and (2) the [redacted] formed in the combined [redacted] or in the Cape Fear River.

On [redacted], EPA's Director of the Chemical Control Division (Jim Willis) signed the TSCA Section 5(e) Consent Order, and on [redacted], DuPont's representative (James Hoover) signed the Consent Order. The effective date of the Consent Order was [redacted]. (See Exhibit B7 - TSCA Section 5(e) Order [redacted].

On [redacted], DuPont commenced the first commercial production of [redacted] at the Facility. On [redacted], DuPont submitted to EPA's Office of Chemical Safety and Pollution Prevention (OCSPP), a TSCA Notice of Commencement (NOC) for [redacted]. (See Exhibit: B8 – TSCA NOC [redacted]).

On [redacted], DuPont commenced the first commercial production of [redacted] at the Facility. On [redacted], DuPont submitted an NOC to OSCPP for [redacted]. (See Exhibit: B9 – TSCA NOC [redacted].

The following products are associated with the two PMN substances: (1) [redacted] (GX903); and (2) [redacted] (GX905C, GX905D and GX902). (See Exhibit A9 - Document No. 0501F1908562817: Safety Data Sheet – GX902; Exhibit A10 - Document No. 0601F1908562817: Safety Data Sheet – GX905C; Exhibit A11 - Document No. 0701F1908562817: Safety Data Sheet – GX905D; Exhibit A12 - Document No. 0801F1908562817: Safety Data Sheet – GX903; and Exhibit A13 - Document No. 0901F1908562817: Copies of Product Labels (GX905D, GX902, GX903).

3.3.2.2. [redacted] *Process Discussion*

Based on the PPVE Process Narrative, [redacted] is produced in the PPVE process. The PPVE production process is located at the Vinyl Ether North area of the Facility. The [redacted] is transported from the PPVE process area via [redacted] for use as a [redacted] process for production of the PMN substances ([redacted]).

According to the [redacted] Process Summary, the production of [redacted] and [redacted] involves [redacted] steps including: [redacted]. In addition to the [redacted] process description below, for details on the production of the two PMN substances in the [redacted] process, see Exhibit B11 - [redacted] Process Flow Diagram and Exhibit B12 - [redacted] Process Summary.

[redacted]

[redacted]

Based on the discussions with Chemours during the inspection and as referenced in the [redacted] Process Flow Diagram, [redacted]. For details on the release, containment and disposal of effluent from the [redacted] process, see Exhibit B11 - [redacted] Process Flow Diagram and Exhibit B12 - [redacted] Process Summary.

In addition, as referenced in the [redacted] Process Summary regarding air emissions, [redacted] For details on air emissions, see Exhibit B11 - [redacted] Process Flow Diagram, Exhibit B12 - [redacted] Process Summary and Exhibit B42 - Air Emission Data.

The following feedstocks are used in the [redacted] process: (1 [redacted]; (2) [redacted]; and (3) [redacted].

The EPA regulates the manufacture, processing, use, distribution in commerce, disposal, and release of the GenX chemicals [[redacted] and [redacted] (GX902[redacted])], pursuant to the Consent Order.

3.3.2.3. TSCA 5(e) [redacted] *Consent Order Discussion*

Terms

Prohibition

Based on the Consent Order, DuPont/Chemours was prohibited from manufacturing or importing [redacted] and [redacted] beyond the production limits as referenced in the Consent Order unless they (DuPont/Chemours) conducted the studies referenced in the Consent Order and submit all the final reports. On or about [redacted], DuPont submitted to the EPA, the final reports for the trigger testing requirements as referenced in Section II (d) of the Consent Order. (See Exhibit B13 – DuPont December 10, 2010, Letter).

On April 27, 2011, DuPont submitted the [redacted] (See Exhibit B14 – DuPont April 27, 2011, Letter). On or about August 1, 2011, the EPA acknowledged the receipt of the studies and determined that [redacted]. The EPA's letter also indicated that DuPont had fulfilled its obligations under the Consent Order for [redacted] (See Exhibit B15 – EPA August 1, 2011, Letter)

Testing

TSCA Section 8(e) Reporting: Based on the Consent Order, any information on the PMN substances ([redacted]) which reasonably supports the conclusion that the PMN substances present a substantial risk of injury to health or the environment is required to be reported under the TSCA Section 8(e) policy statement found at 43 Federal Register 11110 (March 16, 1978), as amended at 52 Federal Register 20083 (May 29, 1987), shall reference the appropriate PMN identification number for the substance and shall contain a statement that the substance is subject to a consent order.

As indicated previously in the PPVE process discussion section of this report, based on the PPVE Process Narrative: [redacted] Subsequent to the inspection, Region 4 requested information from Chemours concerning the date when they became aware that the PMN substances were either released to the Cape Fear River or formed in the Cape Fear River. Chemours response referenced the date [redacted] they spun off from DuPont. For details on the release/forming of the PMN substances in the WWTP or Cape Fear River, see Exhibit B3 – PPVE Process Narrative.

As also indicated in the PPVE process discussion section of this report, on August 15, 2017, Region 4 requested additional information from Chemours as a follow up to the June 2017 inspection, The request was as follows: "Regarding the PPVE process, when (date) did Chemours become aware that the GenX chemicals were being released to the Cape Fear River or formed in the Cape Fear River? For the period prior to the TSCA Inspection, if Chemours has analytic data/sample results of: (A) the earliest signs of Dimer Acid Fluoride (DAF) contamination in the PPVE sumps; or (B) earliest releases/forming of GenX chemicals in the Cape Fear River, please submit those records to the EPA."

On September 1, 2017, Chemours' response indicated that [redacted], (See Exhibit B4 - Chemours September 1, 2017, letter to the EPA). Chemours did not indicate when they first became aware the [redacted] and/or [redacted] was released into the Cape Fear River and/or formed in the Cape Fear River. In addition, during the June 15, 2017, public meeting between Chemours and North Carolina's local and state officials, Chemours

indicated they have been aware since 1980, that GenX was released to the Cape Fear River as a byproduct. During the inspection, the Region 4 Inspection Team asked Chemours about the chemical substance that was discovered in the Cape Fear River. Chemours stated that [redacted].

Chemours did not provide any records or documentation in response to the EPA's requests regarding when they first became aware of the release/forming of the PMN substances ([redacted]) in the Cape Fear River.

Protection in the Workplace

Chemours has the following dermal protective items for use in the [redacted] process area: gloves; full body chemical protective clothing; chemical goggles or equivalent eye protection; and clothing which covers other exposed area of the arms, legs and torso. Chemours provided documentation demonstrating [redacted] (See Exhibit B16 – Chemours Permeation Testing).

Respiratory Protection: Initially, for the [redacted] process area associated with [redacted], the Consent Order required the use, at a minimum, of a [redacted]. On August 20, 2009, DuPont requested the EPA's approval to use [redacted] (See Exhibit B17 – DuPont August 20, 2009, Letter). On February 1, 2010, the EPA modified the Consent Order in response to DuPont's request by authorizing: [redacted]. In the February 1, 2010, letter, the EPA also approved DuPont's request to use [redacted]. (See Exhibit B18 – EPA February 1, 2010, Modification of Order).

New Chemical Exposure Limit (NCEL)

The NCEL section of the Consent Order details an [redacted]. In order to deviate from the respirator requirements, certain criteria must be met:

[redacted]

As stated in the Protection in the Workplace, Respiratory Protection discussion above, the EPA reviewed DuPont's request and stated the use of [redacted] met the *Selection of Appropriate Respiratory Protection* for measured concentrations less than or equal to [redacted] NCEL.

Performance Criteria for Sampling and Analytical Method

The initial calibration language in the Consent Order was also modified. The original language stated: "… the initial calibration shall at a minimum consist of five (5) calibration standards…" The revised Consent Order states the method utilized six calibration standards. Further, the modified order states "… modified calibration ranging from 0.01 to 0.2 x NCEL." Lastly, the Subsequent Calculation text was changed to reflect that the spike must be prepared at [redacted].

Manufacturing

According to the Consent Order, DuPont/Chemours shall not cause, encourage, or suggest the manufacture or import of the PMN substances by any other person. This prohibition shall expire 75 days after promulgation of a final Significant New Use Rule (SNUR) governing the [redacted] and [redacted] under Section 5(a)(2) of TSCA unless DuPont/Chemours is notified on or before a Federal Court action occurs seeking judicial review of the SNUR. Once this prohibition expires, DuPont/Chemours shall notify each person whom it causes, encourages or suggests to manufacture or import the [redacted] and [redacted] of the existence of the SNUR. To date, no SNUR has been promulgated for either chemical EPA identifies as [redacted] or [redacted].

Control of Effluent and Emissions (During the Manufacture of [redacted] and [redacted])

The Consent Order states that DuPont/Chemours "shall recover and capture (destroy) or recycle" the [redacted] and [redacted] "at an overall efficiency of 99% from all the effluent process streams and air emissions (point source and fugitive)."

Based on the [redacted] Process Flow Diagram and [redacted] Process Summary, the [redacted]. Chemours stated that no effluent from the [redacted] process goes to the WWTP.

Regarding the air emissions from the [redacted] process, the [redacted]. For detail, see Exhibit B11 - [redacted] Process Flow Diagram and Exhibit B12 - [redacted] Process Summary.

As reference in the [redacted] process discussion, the air emissions estimate from the [redacted] process is [redacted]. For details on the [redacted] releases (effluent and emission), see the [redacted] process discussion above. In addition, for details on the PPVE release, see the PPVE process discussion above.

Distribution

The Consent Order states DuPont/Chemours shall distribute the [redacted] and [redacted] only to a person who has agreed in writing (prior to distribution) to:

1. Comply with the same requirements and restrictions stated in the Protection in the Workplace and the NCEL sections of the Consent Order;
2. Distribute the [redacted] and [redacted] only to a person who will either recover and capture (destroy) or recycle the [redacted] and [redacted] from all effluent process streams and air emissions (point source and fugitive) at an overall efficiency of 99%; and
3. Distribute the [redacted] in aqueous dispersion of the polymer product or on a heat treated solid product such that the contents polymer residual [redacted] and [redacted] total (anion peak in the MS/MS) are below [redacted] level using the Accelerated Solvent Extraction (ASE) method.

DuPont/Chemours may distribute the [redacted] and [redacted] outside of DuPont/Chemours for temporary transport and storage. Based on the records associated with the distribution and users of [redacted] and [redacted], there was no information showing that any of the PMN substances were temporary transported and stored. The distribution records for both PMN substances show that Chemours shipped them to their production sites in Deep Water, New Jersey (Chambers Works); Washington, West Virginia (Washington Works); or the substances were exported to foreign countries.

Review of safety data sheets for the [redacted] and all products containing the [redacted] indicate distribution of all products to be in aqueous dispersion form. A visual inspection of the [redacted] product storage area by the Region 4 Inspection Team found only final product containers with aqueous products.

Recordkeeping

The Consent Order states that DuPont/Chemours "shall maintain records until 5 years after the date created and shall make them available for inspection and copying by the EPA in accordance with Section 11 of TSCA." The records associated with Chemours compliance with the Consent Order and other sections of TSCA were requested during the inspection and were either provided during the inspection or following the inspection. The records provided to the EPA covered activities that occurred before July 1, 2015, (the date Chemours spun off from DuPont) and activities that occurred on or after July 1, 2015. However, when the EPA requested records pertaining to: (1) when Chemours became aware that the GenX chemicals were being released to the Cape Fear River or formed in the Cape Fear River; and (2) the analytic data/sample results associated with signs of [redacted] contamination in the PPVE sumps, Chemours stated: "[redacted]. Prior to that [redacted]."

Request For Pre-inspection Information

The Consent Order states that the EPA may conduct compliance inspections of DuPont/Chemours facilities and conveyances associated with the [redacted] and [redacted]

[redacted], and that the EPA may contact DuPont/Chemours "in advance to request information pertinent to the scheduling and contact of such inspections." Prior to the inspection, the EPA did contact Chemours to schedule the inspection and provided information requests as part of the NOI letter. Chemours provided most of the information requested in the NOI letter during the inspection. Information that was not readily available to Chemours during the inspection was provided to the inspectors following the inspection. Subsequent to the inspection, Region 4 submitted several information requests to Chemours and Chemours responded to the requests in phases.

Successors Liability Upon Transfer of Consent Order

On or about February 6, 2015, DuPont submitted a TSCA Notice of Transfer to the EPA regarding the manufacturing rights and liabilities associated with [redacted] and [redacted]. On or about July 1, 2015, Chemours spun off from DuPont.

3.3.3. Non-GenX Evaluation

3.3.3.1. Exemptions

Low Volume

Based on the records or statements provided to the EPA by Chemours, the Facility did not manufacture or import any chemical substances that were subject to a low volume exemption.

Research and Development

Based on the records or statements provided to the EPA, Chemours did not engage in any research and development activities associated with new chemical substances at the Facility.

Polymer

Based on the records or statements provided to the EPA, Chemours did not submit any polymer exemption notices to the EPA.

3.3.3.2. Bona Fide Intent

Based on the records or statements provided to the EPA, within the past two years, Chemours did not submit any bona fide intent to the EPA for the Facility.

3.3.3.3. Significant New Use Rules

Based on the records provided to the EPA, Chemours manufactured three chemical substances that are subject to a SNUR: (1) [redacted]; (2) [redacted]; and (3) [redacted].

[redacted]

Based on the results of the EPA's review of Chemours' production records and TSCA 2016 Chemical Data Reporting (CDR) submission, Chemours manufactured [redacted]. [redacted] is subject to a SNUR promulgated at 40 CFR § 721.[redacted]. The effective date of the [redacted] SNUR is [redacted]. Pursuant to 40 CFR § 721.[redacted], the significant new use for [redacted] is any use other than as an [redacted]. Pursuant to 40 CFR § 721.[redacted], an [redacted] is defined as a process that is designed and operated so that [redacted]. A process with [redacted].

Chemours indicated in their August 22, 2017, letter to the EPA: "[redacted]. In 2015, approximately [redacted] of the quantity of [redacted] manufactured at Fayetteville Works was not used on site. Greater than [redacted]. The remaining quantities (i.e., approximately [redacted] pounds) were shipped from Fayetteville Works to [redacted]. Chemours understands that [redacted]." (See Exhibit B19 - Chemours August 21, 2017, Letter).

Based on the process description, flow diagram and use of [redacted], Chemours manufactured [redacted] at the Facility.

The [redacted] report indicated that Chemours manufactured [redacted] pounds of [redacted]. In 2015, approximately [redacted] was used at the Facility and the [redacted]. (See Exhibit B20 – 2016 Amended CDR).

Based on records submitted to the EPA, Chemours provided documentation (Safety Data Sheet) informing the following customers that [redacted] was subject to a SNUR:

[redacted]

The Facility used HFPO as an intermediate in the following onsite fluorinated production processes: PPVE Process; PEVE Process; PSEPVE Process; PMVE Process; EVE Process; Diadduct Ester Process; and HFPO Trimer Process. (See Exhibit B21- Flow Diagrams and Production day/volume).

The columns in the tables below reference: (1) the fluorinated production processes; and (2) CASRNs of the substances (intermediates/raw materials/end products) present in the production of the fluorinated substance.

Production Processes	CASRNs of the Substances Present in Processes
HFPO Trimer (2641-34-1)	
DAF (69116-73-0)	
PEVE (10493-45-3)	

Production Processes	CASRNs of the Substances Present in Processes
Diadduct (4089-58-1) PSEPVE (16090-14-5)	
EVE (63863-43-4)	
PMVE (1187-93-5)	

Chemours used HFPO as an intermediate in each of the fluorinated processes referenced in the tables above. As of , (the effective date), HFPO was subject to a SNUR promulgated at 40 CFR § 721.4160. Pursuant to 40 CFR § 721.4160(a)(2), a significant new use is any use other than as an intermediate in the manufacture of fluorinated substances in an enclose process. As referenced in 40 CFR § 721.4160(b)(1)(i), an enclosed process means a process that is designed and operated so that there is no intentional release of any substance present in the process. In addition, a process .

The North Carolina Department of Environmental Quality (NC DEQ) obtained air emission estimates data for the PPVE North/South and [redacted] process areas generated from Chemours' website. The air emission estimates projected the potential for the release of nine chemical substances associated with the [redacted] processes. (See Exhibit B22- Air Emission Estimates).

The following CASRNs are [redacted] that are present in the [redacted]: [redacted]. Chemours' air emission estimates for 2012 through 2016 projected the release of these chemical substances when used in a [redacted] production process.

The table below (2012 – 2016 air emissions estimates) references: (1) Chemours designated Emission Point IDs; (2) the substances present in the [redacted] that could potentially be released to the air; and (3) projected annual releases (pounds) of the substance present in the [redacted] processes.

Emission Point ID	Substances Present in [redacted] Processes Released to Air	2012 (Pounds)	2013 (Pounds)	2014 (Pounds)	2015 (Pounds)	2016 (Pounds)
NEP-Hdr1 & NEP-Hdr2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
NEP-Hdr1 & NEP-Hdr2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
NEP-Hdr1, NEP-Hdr2 and AEP-A1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
NEP-Hdr1 & NEP-Hdr2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
NEP-Hdr1 & NEP-Hdr2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
NEP-Hdr1 & NEP-Hdr2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
NEP-Hdr1 & NEP-Hdr2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
NEP-Hdr1 & NEP-Hdr2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
NEP-Hdr1 & NEP-Hdr2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Based on Chemours' air emission estimates, it is projected that the chemical substances referenced above (substances present in the [redacted] processes) could potentially be released to the air. Pursuant to 40 CFR § 721.[redacted] (SNUR), [redacted] can only be used [redacted]

intermediate in the manufacture of fluorinated substances in an enclosed process. The projected release of significant quantities of air emissions associated with the chemical substances referenced in the table above, may constitute a significant new use of HFPO. Pursuant to 40 CFR § 721.5(a)(1), "A person who intends to manufacture, import, or process for commercial purposes a chemical substance identified in a specific section" 40 CFR Part 721, Subpart E, "and intends to engage in a significant new use of the substance identified in that section" must submit a significant new use notice (SNUN) as specified under the provisions of Section 5(a)(1)(B) of TSCA, 40 CFR Part 720 and 40 CFR § 721.25. Based on a review of the EPA records regarding submissions for HFPO, DuPont/Chemours did not submit a SNUN to the EPA. Based on the projected air emission release (estimates) associated with the chemicals present in the fluorinated processes, Chemours did not submit SNUN to the EPA at least 90 days prior to using HFPO as an intermediate in an unenclosed process in the production of fluorinated substances. The processes are located in the process areas.

Based on Chemours records associated with the use of , between July 1, 2015 and June 29, 2017, Chemours used days for a combined total of pounds of . For those days when Chemours used/consumed , the daily amount consumed ranged from pounds. To determine the amount of that was actually used on a daily basis between July 1, 2015 and June 29, 2017, see Exhibit B40 - Production and Use.

COF2

In , DuPont submitted a consolidated PMN to the EPA to manufacture . The EPA identified the PMNs as and . The two PMN substances are present in the production process (See Exhibit B37- Block Diagram for).

The EPA's confidential records associated with DuPont's consolidated PMN for PEPF/PEVE (P-94-2074/P-94-2075) available through EPA's Virtual Desktop Infrastructure (VDI) system identifies COF2 as a raw material used in the production of PEVE. A review of the PEVE process provided to the EPA subsequent to the inspection revealed that COF2 was not included in the PEVE Summary Block Diagram also provided (See Exhibit: B23 Chemours September 6, 2017, letter and PEVE Summary Block Diagram). COF2 is manufactured in Chemours' HFPO process (See Exhibit B38-HFPO Flow diagram and P-94-2074 information in EPA's VDI system). PEVE is produced for commercial purpose. In addition, based on Chemours' March 29, 2018, letter (see Exhibit 41 – March 29, 2018 Letter), is also used as .

As of January 1994, COF2 was subject to a SNUR promulgated at 40 CFR § 721.2084. Based on the SNUR promulgated at 40 CFR § 721.2084, COF2 is restricted to an annual production limit of 10,000 pounds. Manufacture, import, or processing of more than 10,000 pounds per year is subject to reporting as a significant new use.

Chemours' letter dated September 6, 2017, listed several factors (use, production, pollution prevention, and hazard assessment) associated with the PMN submission as it relates to COF2. See Exhibit: B23 – Chemours September 6, 2017 Letter.

Based on the EPA records, there is no record on file indicating that either Chemours or its predecessor (DuPont) submitted a SNUN to the EPA for COF2. Chemours' September 6, 2017, letter indicated:

(1) a consolidated PMN describing the use of COF2 was submitted by DuPont in 1994;

(2) the consolidated PMN would have been reviewed by staff in the TSCA new chemicals program who also has the responsibility for review of significant new use notifications received by the Agency;

(3)

(4)

(5)

(6)

(7) COF2 is used as a non-isolated intermediate which is consumed in the course of a reaction.

In its September 6, 2017 Letter, Chemours did not state that a SNUN was submitted to the EPA for COF2. Instead, in the letter/summary, Chemours stated that, "the Company is not responsible for providing any further notification to the Agency with respect to its continued use of Carbonyl Fluoride in the manner described in its September 1 correspondence to EPA Region 4." For detail and confirmation of Chemours statement, see Exhibit B23 - September 6, 2017, Letter and Exhibit B4 - September 1, Letter. Pursuant to 40 CFR § 721.5(a)(1), a person who intends to manufacture, import, or process for commercial purposes a chemical substance identified in a specific section in 40 CFR Part 721, Subpart E, and intends to engage in a significant new use of the substance identified in that section must submit a SNUN as specified under the provisions of Section 5(a)(1)(B) of TSCA, 40 CFR Part 720 and 40 CFR § 721.25. Based on the HFPO/COF2 production records, on July 16, 2015, Chemours exceeded the SNUR annual production limit (10,000 pounds). Based on EPA's review, Chemours did not submit a SNUN as required pursuant to the provisions of TSCA Section 5(a)(1)(B), 40 CFR Part 720 and 40 CFR § 721.25.

Chemours letter dated October 4, 2017, stated COF2 and PAF) are produced as non-isolated intermediates in the HFPO unit and fed to the Vinyl Ether South unit through an enclosed process for use as an intermediate in the production of PMVE and PEVE. The October 4, 2017 Letter (Exhibit B34) also stated if the Vinyl Ether South unit is not running all COF2/PAF from the HFPO unit are treated as a waste and vented to and captured by the Division waste gas scrubber.

Based on production records for HFPO and COF2, between July 5, 2015, and July 16, 2015 (11 day period), Chemours manufactured a total of 78,218 kgs (172,079 pounds) of HFPO. During this period (July 5, 2015 and July 16, 2015), the production of HFPO generated 6.4 percent (11,013 lbs) COF2. According to the March 29, 2018 Letter (Exhibit B41), COF2 was used as a feedstock in the production of PMVE. PMVE was manufactured for commercial purpose. Based on HFPO/COF2 production records, on July 16, 2015, Chemours exceeded the 10,000 pound threshold production limit for COF2. Between July 16, 2015, and June 29, 2017, Chemours manufactured COF2 (for a total of 646 days). Between July 16, 2015, and June 29, 2017, the daily production range for COF2 was 10 kgs to 515 kgs. To determine the amount of COF2 that was produced on a daily basis between July 16, 2015, and June 29, 2017, see Exhibit B40 - HFPO Production and Use and Exhibit B41 – March 29, 2018 Letter.

A review of the P&IDs shows [redacted] and [redacted] were transferred from the [redacted] unit to [redacted] unit by way of [redacted]. For details on the transfer of [redacted] and [redacted], see Exhibits B43 and B44 - P&ID ([redacted]).

[redacted]

The production records indicated [redacted] was manufactured at the Facility. [redacted] is subject to a SNUR promulgated at 40 CFR § 721.[redacted]. The effective date of the SNUR for [redacted] was [redacted]. The significant new use for [redacted] includes the manufacture (including import) or processing for [redacted]. The manufacture (including import) or processing of [redacted].

Chemours indicated [redacted]. In the reaction process, [redacted]. Based on Chemours' 2016 CDR report, [redacted] was used at the Facility as [redacted].

[redacted] P-95-0980)

In 1995, DuPont submitted a PMN to the EPA to manufacture a chemical that the EPA identified as P-95-0980 for use as an intermediate in the production of E-2-solvent (end product). At the time of the PMN submission, E-2-solvent was listed on the TSCA inventory, but the intermediate (P-95-0980) was not listed on the TSCA inventory (See Exhibit: B25- Chemours October 13, 2017, Letter).

Based on Chemours' 2016 CDR report, between 2012 and 2015, DuPont/Chemours manufactured the E-2-solvent. This means DuPont manufactured the intermediate (P-95-0980) before they manufactured the E-2-solvent.

A review of EPA's confidential database (VDI) revealed DuPont did not submit a Notice of Commencement (NOC) to EPA when P-95-0980 was manufactured for commercial purpose as

an intermediate in the production of the E-2-solvent. This means P-95-0980 was not added/listed on the TSCA inventory.

The production of E-2-solvent is a continuous process. Between October 10, 2015, and November 27, 2015, Chemours manufactured 24,429 pounds of E-2-solvent for commercial purpose. The production record did not reference the amount of P-95-0980 that was produced during the production of E-2-solvent. During the production period (October 10, 2015, and November 27, 2015), the record did not indicate the actual number of days E-2-solvent was produced. For details on the production volume associated with of E-2-solvent, see Exhibit B26- July 31, 2017 Letter).

Based on EPA's certified statement (ER-18-5001), P-95-0980 is not listed on the TSCA inventory. According to the certified statement, P-95-0980 is regulated under a TSCA Section 5(a)(2) SNUR (See Exhibit B27- TSCA Certified Statement). Pursuant to 40 CFR Part 720, a chemical substance that is not listed on the TSCA inventory is classified as a new chemical substance. Pursuant to 40 CFR Part 720, manufacturers, including importers, must submit a PMN for a new chemical substance at least ninety (90) days prior to the first commercial production.

A review of the E-2- solvent process flow diagram shows P-95-0980 as a non-isolated intermediate. (See Exhibit B25- Chemours October 13, 2017, Letter). Based on the P-95-0980 submission, P-95-0980 is actually an intermediate that is used in the production of the E-2-solvent. Since P-95-0980 was not listed on the TSCA Inventory when it was produced for commercial purpose, Chemours was required to submit a PMN to the EPA for P-95-0980 pursuant to 40 CFR § 720,22. Based on EPA's confidential records (VDI), Chemours did not submit a PMN for P-95-0980.

3.4. TSCA Section 8 Evaluation

3.4.1. Preliminary Assessment Information Rule (PAIR)

Based on the records provided to EPA, Chemours did not manufacture, import, or use any chemical substance that was subject to reporting under PAIR.

3.4.2. Allegation of Significant Adverse Reaction

Based on the discussions with Chemours representatives and review of the records for the past two years, there was no allegation of significant adverse reaction on file for the chemical substances manufactured, imported, processed or distributed at the Facility.

3.4.3. Health and Safety Studies

Based on the discussions with Chemours representatives regarding health and safety studies, Mr. Johnson indicated they would check with the corporate officials to confirm the status of studies. Chemours did not include any health and safety studies in their response.

3.4.4. Substantial Risk to Human Health/Environment

During the inspection, the inspection team inquired about: (1) documentation of allegations of adverse reactions that may be subject to TSCA Section 8(c) reporting; (2) a list of Section 8(d) health and safety studies submitted to EPA and copies of any known health and safety information that were not submitted to EPA; and (3) any substantial risk information not known to EPA (TSCA Section 8(e)). At the time of the inspection, Chemours indicated they had no such records as referenced above, and they would check with their corporate office in Delaware, and, if applicable, they would submit the records to EPA and ERG. No records pertaining to TSCA Sections 8(c), 8(d) or 8(e) were submitted to Region 4 or ERG.

As discussed in Section 3.3.1 (PPVE Process) above, the effluent from the PPVE process contains the PMN substance ( ) and depending on the pH level in the combined effluent to the outfall the may convert to the other PMN substance ( ) which is discharged into the Cape Fear River. During a public meeting on June 15, 2017, between Chemours and the New Hanover County Board of Commissioners, Chemours indicated that dating back to 1980; GenX (which Chemours referred to as a byproduct) was also a component in the wastewater discharged to the Cape Fear River.

The Consent Order (page 4, Testing) indicates that any information on the PMN substances (and) which reasonably supports the conclusion that the PMN substances present a substantial risk of injury to health or the environment is required to be reported under EPA's TSCA Section 8(e) policy statement at 43 Federal Register 11110 (March 16, 1978) as amended at 52 Federal Register 20083 (May 29, 1987), and shall reference the appropriate PMN identification number for this substance and shall contain a statement that the substance is subject to a consent order. (See Exhibit A15 – Federal Register, May 29, 1987)

As discussed in the PPVE process (Section *3.3.1.2),* Chemours did not provide any record as to when they first became aware that the PMN substances (and) were either released from the WWTP or formed in the Cape Fear River.

3.4.5. Chemical Data Reporting

3.4.5.1. CDR Introduction

On September 20, 2016, Chemours submitted a TSCA 2016 CDR report for chemical substances. Based on EPA's review of Chemours' 2015 production volumes and comparison with the submitted CDR report, the following chemical substances were not reported to two significant figures of accuracy on the 2016 CDR: (1) ; (2) ; and (3) . After June 29, 2017, without notice from the EPA, on August 3, 2017, Chemours submitted an amended CDR (revising production volumes) for: ; ; and . In addition to Chemours 2016 CDR submission, Chemours did not include the following chemical substances on the 2016 CDR: (1) ; (2) ; and (3) .

3.4.5.2. CDR Discussion

Based on the 2015 production records, Chemours manufactured pounds of . The original 2016 CDR report indicated pounds of

were produced in 2015. The amended 2016 CDR report indicated [redacted] pounds of [redacted] were produced (See Exhibit B28 - 2016 Original CDR and Amended CDR).

Based on the amended 2016 CDR and EPA's calculation, the original 2016 CDR was not reported to two significant figures of accuracy.

For calendar year 2015, [redacted] was over-reported on the 2016 CDR.

[redacted]

Based on the 2015 production records, Chemours manufactured [redacted] pounds of [redacted]. The original 2016 CDR report indicated [redacted] pounds of [redacted] were produced in 2015. The amended 2016 CDR report indicated [redacted] pounds of [redacted] were produced (See Exhibit: B29 -2016 Original CDR and Amended CDR).

Based on the amended 2016 CDR and EPA's calculation, the initial 2016 CDR was not reported to two significant figures of accuracy.

For calendar year 2015, [redacted] was under-reported on the 2016 CDR.

[redacted]

Based on the 2015 production records, Chemours manufactured [redacted] pounds of [redacted]. The 2016 original CDR report indicated [redacted] pounds of [redacted] were produced in 2015. The amended 2016 CDR report indicated [redacted] pounds of [redacted] were produced (See Exhibit: B30 - 2016 CDR, and amended CDR).

Based on the amended 2016 CDR, and EPA's calculation, the initial 2016 CDR was not reported to two significant figures of accuracy.

For calendar year 2015, [redacted] was under reported on the 2016 CDR.

[redacted]

Based on the PPVE Process Narrative, the PPVE Flow Chart and the [redacted] Production Block Diagram, during the first step of the [redacted] process, the [redacted] (See Exhibit A7 - PPVE Flow Chart, Exhibit B2 - [redacted] and B3 - PPVE Process Narrative).

In the second step of the PPVE process, the [redacted]

[redacted]. (See Exhibit A7 - PPVE Flow Chart, Exhibit B2 - [redacted] Production and B3 - PPVE Process Narrative).

In an effort to confirm whether the [redacted] used to produce [redacted] is actually [redacted], on August 14, 2017, Region 4 requested additional information from Chemours via email and in a letter dated August 15, 2017 (See Exhibit B31 - EPA August 15, 2017 Letter). The request was as follows: "Regarding the PPVE process, the flow diagram shows that the [redacted] goes either to a [redacted] for use in the [redacted] production process or it is used in the subsequent steps to produce [redacted]. Based on the review of the PPVE diagram, it appears that the [redacted] that is used to produce [redacted] can be classified as a [redacted]. If Chemours classified the [redacted] as an [redacted], please explain the isolation of the [redacted] in the [redacted] process."

On August 22, 2017, Chemours provided an explanation on the 2016 CDR report for [redacted]. The statement is as follows: "The quantities of [redacted] that are used [redacted]. However, [redacted].

For purposes of the 2016 CDR report, Chemours indicated that they [redacted]. Chemours is treating the entire production of [redacted] as an isolated intermediate. (See Exhibits: B33- Chemours July 31, 2017 letter).

Region 4 first became aware there was an additional step/process between the [redacted] when Chemours submitted a response letter dated August 22, 2017. As a result, on September 20, 2017, Region 4 requested the following information from Chemours: "[redacted]

On October 4, 2017, Chemours responded to Region 4's request. Chemours response indicated: [redacted]

Based on the Chemours October 4, 2017 letter, in 2015, [redacted] (See Exhibit B34 – Chemours' October 4, 2017, Letter and Exhibit B35 – PPVE Flow Chart).

In an attempt to identify the actual location of the [redacted], Region 4 and ERG reviewed the PPVE P&ID. Based on the review of the P&ID, the EPA was able to locate [redacted]. However, on the same day (August 14, 2017) that Region 4 inquired about the [redacted] of [redacted] process, Chemours made a revision to the system associated with [redacted]. (See Exhibit B36 - P&ID # W553421). P&ID # W553421 shows that on August 14, 2017, there was a revision associated with the [redacted]. Based on the EPA's review of the [redacted] production process, Chemours classified [redacted] as an [redacted].

[redacted]

In [redacted], DuPont submitted a consolidated PMN to EPA to manufacture [redacted] and [redacted]. As referenced in the PMN, [redacted] was used as an [redacted] for production of [redacted]. The EPA identified the PMNs as [redacted]. DuPont submitted a TSCA NOC for both PMN substances. In 2012, DuPont submitted a TSCA 2012 CDR report to the EPA for both PMN substances [[redacted]] that were produced at the Facility.

In 2015, Chemours used the same production site (the Facility) to produce both chemicals substances. Chemours included [redacted] on the TSCA 2016 CDR, but failed to report the [redacted] ([redacted]) that was used to produce [redacted].

Chemours' Block Diagram for [redacted] shows [redacted] as a [redacted] being transferred to a [redacted] Based on the PMN submission, [redacted] is an [redacted]. (See Exhibit B37 - [redacted] Block Diagram).

Based on the Chemours' March 29, 2018 Letter (Exhibit B41), Chemours does [redacted] generated as a [redacted], The March 29, 2018 Letter also indicated between July 1, 2015, and June 29, 2017, Chemours [redacted]. Based on the 2015-2017 production volume for [redacted], Chemours manufactured a reportable [redacted] in 2015. Pursuant to 40 CFR § 711.5, a report must be submitted for any chemical substance that is on the TSCA Master Inventory File at the beginning of a submission period described in § 711.20, unless the chemical substance is specifically excluded by § 711.6. [redacted] was on the TSCA Master Inventory at the beginning of a submission period and based on the [redacted] submission, [redacted] was not exempt from the 2016 CDR requirements. Chemours did not include [redacted] in the Facility's 2016 CDR, as required by 40 CFR § 711.5.

[redacted]COF2

In 2015, Chemours manufactured [redacted] during the production of [redacted]HFPO. Based on the [redacted]HFPO Block Flow Diagram, [redacted]COF2 is a [redacted]byproduct that is transferred to the [redacted]Vinyl Ether South unit for use in the production of either [redacted]PMVE or [redacted]PEVE (See Exhibit: B38 - [redacted]HFPO Block Flow Diagram). In addition, the [redacted]HFPO production summary indicated certain [redacted]byproducts generated during the [redacted]HFPO2 reaction [[redacted] and [redacted]] also are [redacted]removed during distillation as part of an [redacted]enclosed, continuous process for use at the Vinyl Ether South unit as non-isolated intermediates [redacted]in the manufacture of PMVE and PEVE (See Exhibit B4 - Chemours September 1, 2017 Letter to the EPA).

Based on the information referenced in the HFPO Block Flow diagram and written response (summary), [redacted] is a byproduct that was transferred from the HFPO process to the PEVE/PMVE process reactor for use as a raw material in the PEVE/PMVE process. In addition, as referenced in P-94-2074 (PEPF), [redacted] is also listed as a raw material for production of PEVE. For details on the use of COF2, see P-94-2074 and P-94-2075 in EPA's VDI and Exhibit B41).

Based on the 2016 CDR approximately 4.5 million pounds of HFPO were produced in 2015. Based on the Chemours' March 29, 2018 Letter, the production of HFPO yielded 6.4 percent COF2. That meant that approximately 288,000 pounds of COF2 were produced in 2015 (See Exhibit B41). Chemours' letter dated October 4, 2017, stated COF2 and PAF are produced as non-isolated intermediates in the HFPO unit and feed to the Vinyl Ether South unit through an enclosed process for use as an intermediate in the production of PMVE and PEVE. The October 4, 2017 Letter (Exhibit B38) also stated if the Vinyl Ether South unit is not running all COF2/PAF from the HFPO unit are treated as a waste and vented to and captured by the Division waste gas scrubber. For details on the production, use and release/disposal of COF2 see Exhibit B34 - October 4, 2017 Letter. Chemours did not include COF2 in the Facility's 2016 CDR that was submitted to the EPA, as required by 40 CFR § 711.5. Based on Chemours 'March 29, 2018 Letter (Exhibit 41), [redacted] is used as an [redacted] to produce [redacted].

A review of the P&IDs shows [redacted] and [redacted] were transferred from the [redacted]. For details on the transfer of [redacted], see Exhibits B43 and B44 - P&ID ([redacted]).

PAF

In 2015, Chemours manufactured PAF during the production of HFPO. Based on the HFPO Block Flow Diagram, PAF is a byproduct that is transferred to the Vinyl Ether South unit for use in the production of either PMVE or PEVE (See Exhibit B38 - HFPO Block Flow Diagram). In addition, the HFPO production summary indicated certain byproducts generated during the HFP:O2 reaction [COF2 and PAF] process also are removed during distillation as part of an enclosed, continuous process for use at the Vinyl Ethers South unit as non-isolated intermediates in the manufacture of PMVE and PEVE. (See Exhibit B4 - Chemours September 1, 2017, Letter to the EPA).

Based on the information referenced in the HFPO Block Flow Diagram and Chemours' written response (summary), PAF is a byproduct that is transferred from the HFPO process to the PEVE/PMVE process reactor for use as a raw material in the PEVE/PMVE process. In addition, as referenced in P-94-2074 (PEPF), PAF is also listed as a raw material for production of [redacted]. (See P-94-2074 in EPA's VDI and Exhibit B37 - PEVE Block Diagram).

Based on the 2016 CDR, approximately 4.5 million pounds of HFPO were produced in 2015. Based on Chemours March 29, 2018 Letter, the production of HFPO yielded 7.4 percent PAF. This means approximately 333,000 pounds (7.4 percent) of PAF were produced in 2015 (See Exhibit B41). Chemours' letter dated October 4, 2017, stated COF2 and PAF are produced as non-isolated intermediates in the HFPO unit and feed to the Vinyl Ether South unit through an enclosed process for use as an intermediate in the production of PMVE and PEVE. The October 4, Letter (Exhibit B34), also stated if the Vinyl Ether South unit is not running all COF2/PAF from the HFPO unit are treated as a waste and vented to and captured by the

[redacted]. For details on the production, use and release/disposal of [redacted], see Exhibit B34 - October 4, Letter. Chemours did not include [redacted] in the 2016 CDR that was submitted to the EPA as required by 40 CFR § 711.5. Based on Chemours' March 29, 2018 Letter (Exhibit B41), [redacted] is used as an [redacted] to produce [redacted].

A review of the P&IDs shows [redacted] were transferred from the [redacted]. For details on the transfer of [redacted] and [redacted], see Exhibits B43 and B44 - P&ID ([redacted]).

[redacted]

In 2011, DuPont manufactured [redacted] at the Facility. DuPont included [redacted] in their 2012 CDR. In 2015, Chemours used the same production site (the Facility) to produce [redacted] as an [redacted] for the production of [redacted] and [redacted]. For details on the production/use of [redacted], see Exhibit B 45 - Co-production of [redacted].

Based on the production volume for the other [redacted] that is used in the [redacted] and [redacted] processes, Chemours may have produced a reportable quantity (greater than 25,000 pounds) of [redacted]. Pursuant to 40 CFR § 711.5, a report must be submitted for any chemical substance that is on the TSCA Master Inventory File at the beginning of a submission period described in § 711.20, unless the chemical substance is specifically excluded by § 711.6. [redacted] was on the TSCA Master Inventory at the beginning of a submission period. Chemours did not include [redacted] in the Facility's 2016 CDR, as required by 40 CFR § 711.5. Based on Exhibit B 45, [redacted]

3.5. TSCA Section 12 Evaluation

Customers (foreign and domestic) that processed [redacted] (GX903 and Various Concentrations of [redacted] (GX902, GX905C and GX905D)):

GenX Acid (GX903) is shipped to Chemours Chambers Works facility in Deep Water, New Jersey.

GenX Salt (GX905C, GX905D & GX902) is shipped to Chemours Washington Works facility in Washington, West Virginia.

GenX Salt (GX905C, GX905D & GX902) is exported to the Netherlands.

GenX Acid (GX903) and GenX Salt (GX905C, GX905D & GX902) are exported to Japan. GenX Salt (GX905D & GX902) is exported to China.

GenX Salt (GX905D & GX902) is exported to India.

Export notices dating back to 2015 were submitted to the EPA (See Exhibit: B10 – GenX Customer List).

3.6. TSCA Section 13 Evaluation

As a follow up to the EPA's June 22, 2017, NOI, during the inspection, the EPA inspection team asked Chemours if the Facility imported any chemical substance in the past four years. See Exhibit A1 - NOI. Chemours stated that all chemical import activities are controlled by the corporate office in Wilmington, Delaware. As a result, Chemours did not provide any records on the import of chemical substances associated with the Facility.

Subsequent to the inspection and through coordination with Region 4's Resource Conservation and Restoration Division, it was disclosed to Region 4's TSCA New and Existing Chemicals Program that the Facility received imported spent [redacted], a [redacted]. The importation of [redacted] was discussed further with representatives from EPA Headquarters Office of Pollution Prevention and Toxics (OPPT).

On January 22, 2018, OPPT submitted a written request for information to Chemours regarding the reclamation of [redacted] and [redacted]. The EPA requested the following information: (1) Time period (dates of reclamation); (2) The origin of the waste material ([redacted]) and the amount; (3) The reclamation process including process diagrams; (4) The name of the compounds and the amount processed daily; (5) The disposition of the reclaimed materials (end use); (6) The on-site emission point sources and daily release; and (7) Applicable statutory reporting requirements for the reclaimed materials ([redacted] and [redacted]).

On February 2, 2018, Chemours submitted their response to OPPT's concerns. On or about March 1, 2018, OPPT submitted a copy of Chemours' response to Region 4. Based on Chemours response, the spent [redacted] that was imported for reclamation was included on Chemours Corporate Headquarter 2016 CDR. A review of the EPA's confidential CDR database (VDI) revealed Chemours' Corporate Headquarter submitted a 2016 CDR report for the imported [redacted]. For details on the import and reclamation of [redacted] and [redacted], see Exhibit 46 - February 2, 2018 Letter.

The remainder of this page is intentionally blank

4.0. REPORT APPROVAL

4.1. Report – Primary Author

Verne George Lead TSCA Inspector U.S. EPA Region 4 Chemical Management and Emergency Planning Section	Date

4.2. Report - Co-Authors

Daryl Hudson TSCA Inspector (Contractor to EPA) Eastern Research Group, Inc.	Date
Keith Bates Inspector/TSCA CBI DCO U.S. EPA Region 4 Chemical Management and Emergency Planning Section	Date

4.3. Report – Technical Reviewer

Gopal Timsina Inspector/TSCA CBI ADCO U.S. EPA Region 4 Chemical Management and Emergency Planning Section	Date

4.4. Report - Approver

Robert W. Bookman Chief U.S. EPA, Region 4 Chemical Management and Emergency Planning Section	Date

To: Sullivan, Greg[Sullivan.Greg@epa.gov]; Saenz, Diana[Saenz.Diana@epa.gov]
From: Miles, James
Sent: Fri 6/1/2018 4:48:39 PM
Subject: RE: Notice of Intent - TSCA citizen suit

Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5

From: Sullivan, Greg
Sent: Friday, June 01, 2018 12:44 PM
To: Miles, James <miles.james@epa.gov>; Saenz, Diana <Saenz.Diana@epa.gov>
Subject: RE: Notice of Intent - TSCA citizen suit

Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5

From: Miles, James
Sent: Friday, June 01, 2018 12:39 PM
To: Sullivan, Greg <Sullivan.Greg@epa.gov>; Saenz, Diana <Saenz.Diana@epa.gov>
Subject: RE: Notice of Intent - TSCA citizen suit

Edits below.

Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5

From: Sullivan, Greg
Sent: Friday, June 01, 2018 10:41 AM
To: Miles, James <miles.james@epa.gov>; Saenz, Diana <Saenz.Diana@epa.gov>
Subject: FW: Notice of Intent - TSCA citizen suit

James and Diana – I'd like to provide RAK with an update and next steps. Can you take a look and add/edit as needed. I'd like to send today before I call the region back.

Rosemarie,

FYI - We met with WED yesterday. **Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5**

Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5

Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5

From: Palmer, Leif
Sent: Tuesday, May 29, 2018 2:16 PM
To: Kelley, Rosemarie <Kelley.Rosemarie@epa.gov>
Cc: Rubini, Suzanne <Rubini.Suzanne@epa.gov>; Sullivan, Greg <Sullivan.Greg@epa.gov>
Subject: Fwd: Notice of Intent - TSCA citizen suit

Hi — our internet is out. Please see the email from DOJ. Greg, I left you a voicemail about this.

Sent from my iPhone
Begin forwarded message:

> **From:** "Mann, Martha (ENRD)" <Martha.Mann@usdoj.gov>
> **Date:** May 29, 2018 at 11:54:34 AM EDT
> **To:** "palmer.leif@epa.gov" <palmer.leif@epa.gov>, "Grant.Brian@epa.gov" <Grant.Brian@epa.gov>
> **Cc:** "Cirino, Paul (ENRD)" <Paul.Cirino@usdoj.gov>
> **Subject: Notice of Intent - TSCA citizen suit**
>
> Hello Leif and Brian,
>
> Just checking in to see if you are aware of the attached notice of intent, and whether you have assigned the matter to an attorney in your office.

Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5

> Thanks so much,
> Martha
>
> Martha C. Mann
> United States Department of Justice
> Environment and Natural Resources Division
> 202.514.2664

To: Sullivan, Greg[Sullivan.Greg@epa.gov]; Saenz, Diana[Saenz.Diana@epa.gov]
From: Miles, James
Sent: Fri 6/1/2018 4:46:48 PM
Subject: RE: Notice of Intent - TSCA citizen suit

Yup typo

From: Sullivan, Greg
Sent: Friday, June 01, 2018 12:46 PM
To: Miles, James <miles.james@epa.gov>; Saenz, Diana <Saenz.Diana@epa.gov>
Subject: RE: Notice of Intent - TSCA citizen suit

ERB = ERG?

From: Miles, James
Sent: Friday, June 01, 2018 12:42 PM
To: Sullivan, Greg <Sullivan.Greg@epa.gov>; Saenz, Diana <Saenz.Diana@epa.gov>
Subject: RE: Notice of Intent - TSCA citizen suit

Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5

From: Sullivan, Greg
Sent: Friday, June 01, 2018 12:41 PM
To: Miles, James <miles.james@epa.gov>; Saenz, Diana <Saenz.Diana@epa.gov>
Subject: RE: Notice of Intent - TSCA citizen suit

Good idea. **Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5**

From: Miles, James
Sent: Friday, June 01, 2018 12:39 PM
To: Sullivan, Greg <Sullivan.Greg@epa.gov>; Saenz, Diana <Saenz.Diana@epa.gov>
Subject: RE: Notice of Intent - TSCA citizen suit

Edits below.

Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5

From: Sullivan, Greg
Sent: Friday, June 01, 2018 10:41 AM
To: Miles, James <miles.james@epa.gov>; Saenz, Diana <Saenz.Diana@epa.gov>
Subject: FW: Notice of Intent - TSCA citizen suit

James and Diana – I'd like to provide RAK with an update and next steps. Can you take a look and add/edit as needed. I'd like to send today before I call the region back.

Rosemarie,

FYI - We met with WED yesterday. **Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5**

Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5

Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5

From: Palmer, Leif
Sent: Tuesday, May 29, 2018 2:16 PM
To: Kelley, Rosemarie <Kelley.Rosemarie@epa.gov>
Cc: Rubini, Suzanne <Rubini.Suzanne@epa.gov>; Sullivan, Greg <Sullivan.Greg@epa.gov>
Subject: Fwd: Notice of Intent - TSCA citizen suit

Hi — our internet is out. Please see the email from DOJ. Greg, I left you a voicemail about this.

Sent from my iPhone
Begin forwarded message:

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> **Date:** May 29, 2018 at 11:54:34 AM EDT
> **To:** "palmer.leif@epa.gov" <palmer.leif@epa.gov>, "Grant.Brian@epa.gov" <Grant.Brian@epa.gov>
> **Cc:** "Cirino, Paul (ENRD)" <Paul.Cirino@usdoj.gov>
> **Subject: Notice of Intent - TSCA citizen suit**
>
> Hello Leif and Brian,
>
> Just checking in to see if you are aware of the attached notice of intent, and whether you have assigned the matter to an attorney in your office.

Enforcement/Investigatory / Ex. 7(a) / Deliberative Process / Ex. 5

> Thanks so much,
> Martha
>
> Martha C. Mann
> United States Department of Justice
> Environment and Natural Resources Division
> 202.514.2664

To: Kemker, Carol[Kemker.Carol@epa.gov]; Allenbach, Becky[Allenbach.Becky@epa.gov]
From: Culpepper, Linda
Sent: Sun 7/9/2017 9:49:51 PM
Subject: FW: GenX and Chemours Permit

Hi – can you develop a response for this part of question 3) below, or let me know who I should coordinate with at EPA?

3) Please explain the 2009 Consent Order between EPA and DuPont, and the 2017 First Amendment to Order on Consent.

Does this consent order allow for the discharge of GenX as a by-product at the Fayetteville Works site?

Appreciate your help.
linda

Linda Culpepper
Deputy Director
Division of Water Resources
North Carolina Department of Environmental Quality

1611 Mail Service Center
Phone: 919-707-9014

From: Kemp Burdette [mailto:kemp@cfrw.us]
Sent: Saturday, July 08, 2017 10:36 PM
To: Culpepper, Linda <linda.culpepper@ncdenr.gov>
Subject: Re: GenX and Chemours Permit

Thank you Linda. I wasn't expecting a reply over the weekend! If you can work with EPA that would be great. Thanks again.

Kemp Burdette
Cape Fear Riverkeeper

Please excuse message brevity and typos; sent from my smartphone.

On Jul 8, 2017 9:44 PM, "Culpepper, Linda" <linda.culpepper@ncdenr.gov> wrote:
Hi Kemp - Julie and I will work on the responses to your follow up questions on Monday. The question regarding the EPA Consent Agreement will need an EPA response. Want us to work with EPA on the response, or would you like to work with EPA directly? Either can work for us.

Linda

Sent from my iPhone
On Jul 8, 2017, at 12:08 PM, Kemp Burdette <kemp@cfrw.us> wrote:

Thank you Sheila,

Hi Linda, Jeff, and Julie. Thank you for your help with Chemours permit, NC 0003573. I have a few questions.

1) Can you explain the relationship between DuPont, Chemours, and Kuraray? Which company(s) is/are actually producing GenX either as a commercial product or a waste byproduct? For each company that is producing GenX, please explain how GenX is captured and/or treated? What companies are contributing GenX to the waste stream that is treated on site and then discharged per NPDES Permit # NC0003573. (I understand that Chemours has recently agreed to capture/truck/incinerate GenX, but I am interested in the process immediately prior to this voluntary decision).

2) Please confirm that Chemours, per NPDES Permit # NC0003573, is ultimately responsible for any substance that is discharged from the site, regardless of which of the three companies adds that substance to the waste-stream.

3) Please explain the 2009 Consent Order between EPA and DuPont, and the 2017 First Amendment to Order on Consent. Does this consent order allow for the discharge of GenX as a by-product at the Fayetteville Works site? Did NC DEQ take this document into consideration when writing NPDES Permit # NC0003573? If so, please explain how this document was considered and whether it influenced the terms of the permit.

4) Please explain how the current NPDES permit allows for the discharge of GenX. It is present in the discharge but does not appear to be listed in the Effluent Limitations and Monitoring Requirements - Subpart I. If reporting or monitoring is not required by the NPDES permit are there other requirements for the company to report its discharge of GenX or other perfluorinated compounds and if so, what are those requirements and where can the public access this data?

5) (similar to #3) Please explain how the current NPDES permit allows for the discharge of C8 or PFOA. The 2009 EPA consent order appears to prohibit the discharge of C8 or PFOA and yet it also appears to be present in the discharge. These compounds also do not appear to be listed in the Effluent Limitations and Monitoring Requirements - Subpart I. If reporting or monitoring is not required by the NPDES permit are there other requirements for the company to report its discharge of C8 or PFOA or other perfluorinated compounds and if so, what are those requirements and where can the public access this data?

6) DEQ's sister agency DHHS has determined, based on one European study, that GenX poses a low health risk at levels at or below 70,909 ppt (although among researchers there is a growing consensus that GenX is as toxic as C8 suggesting this level may be high). If DHHS determines that a compound is present at unsafe levels in drinking water how does that finding impact DEQ's permitting process? Has there been communication between DEQ and DHHS regarding the presence of perfluorinated compounds in the Cape Fear River? Please explain how the DHHS assessment will influence the renewal of NPDES Permit # NC0003573. How would DEQ respond if DHHS were to lower the safe concentration determination for GenX, or other perfluorinated compounds, below the concentrations currently found in the river.

7) What is the process for establishing Water Quality Based Effluent Limits for perfluorinated compounds, like GenX?

8) Chemours voluntarily ceased discharging GenX into the Cape Fear River. Given the uncertainty of the impacts to downstream drinking water supplies, what steps is DEQ taking in the permit renewal process to ensure that this discharge is not resumed by the company?

Thanks for your assistance with this important issue.

On Fri, Jul 7, 2017 at 2:51 PM, Holman, Sheila <sheila.holman@ncdenr.gov> wrote:

Kemp,

I am copying Linda Culpepper, Jeff Poupart and Julie Grzyb on this message. Jeff and Julie can answer the NPDES permitting questions. Sorry for the delay in responding.

Sheila

Sent from my Verizon, Samsung Galaxy smartphone

-------- Original message --------

From: Kemp Burdette <kemp@cfrw.us>
Date: 7/7/17 2:38 PM (GMT-05:00)
To: "Holman, Sheila" <sheila.holman@ncdenr.gov>
Subject: Re: GenX and Chemours Permit

Thanks Sheila,

I know you are very busy and I appreciate the hard work you do. Could you connect me to the best person in central permitting regarding questions about the DuPont/Chemours permit? There are a few things I am confused about and I'd like to speak with someone who could help me understand as soon as possible. Thank you.

On Thu, Jul 6, 2017 at 7:18 AM, Holman, Sheila <sheila.holman@ncdenr.gov> wrote:

Kemp,

Thank you for the reminder. Last week was very busy. Let me discuss the public notice and hearing process with DWR staff and I will get back to you on your questions and recommendation for a public hearing.

Sheila

Sheila Holman
Assistant Secretary for the Environment
NCDEQ
1601 Mail Service Center
Raleigh, NC 27699-1601
Phone/Fax: 919-707-8619
deq.nc.gov
Sheila.holman@ncdenr.gov

From: Kemp Burdette [mailto:kemp@cfrw.us]
Sent: Wednesday, July 5, 2017 7:34 PM
To: Holman, Sheila <sheila.holman@ncdenr.gov>
Subject: Re: GenX and Chemours Permit

Sheila,

Just wanted to make sure you saw my previous email. Thanks.

Kemp Burdette
Cape Fear Riverkeeper

Please excuse message brevity and typos; sent from my smartphone.

On Jun 29, 2017 1:41 PM, "Kemp Burdette" <kemp@cfrw.us> wrote:

Hi Sheila,

Good to see you twice yesterday. I wanted to check on one thing related to Chemours Permit. Will the public have an opportunity to give comments on that? Will there be a hearing? I think it would be an important way to show folks that DEQ is listening to their concerns and that the process is transparent. Also, do you have a timeline on any of this and/or for when the permit might be renewed. Feel free to call my cell if that's easier. 910-264-8036. Thanks again!

Kemp Burdette
Cape Fear Riverkeeper

Please excuse message brevity and typos; sent from my smartphone.

--
Kemp Burdette
Cape Fear Riverkeeper
617 Surry Street
Wilmington, NC 28401
o- 910-762-5606
c- Personal Phone / Ex. 6

--
Kemp Burdette
Cape Fear Riverkeeper
617 Surry Street
Wilmington, NC 28401
o- 910-762-5606
c Personal Phone / Ex. 6

To: Michael Pjetraj[michael.pjetraj@ncdenr.gov]; michael.abraczinskas@ncdenr.gov[michael.abraczinskas@ncdenr.gov]
Cc: Mitchell, Ken[Mitchell.Ken@epa.gov]
From: Kemker, Carol
Sent: Wed 6/6/2018 1:02:59 PM
Subject: FW: Citizen Suit Notice (CWA) - Cape Fear River Watch v Chemours Company FC, LLC ("Chemours")" Regarding NPDES Permit NC0003573 & TSCA Consent Order P-08-508/P-08-509 located in Fayetteville, NC – NON EJ POTENTIAL
CapeFearRiverWatch v Chemours_NC.pdf

Mike and Michael,

Attached is the NOI we received regarding Chemours.

Carol

To: Chernikov, Sergei[sergei.chernikov@ncdenr.gov]
Cc: Davis, Molly[Davis.Molly@epa.gov]; Horsey, Maurice[Horsey.Maurice@epa.gov]
Sent: Fri 6/16/2017 5:10:15 PM
Subject: Chemours Plant, NC0003573

Sergi

Can you help me with obtaining some information about this facility.

Facility

FACILITY NAME (1)	CHEMOURS COMPANY-FAYETTEVILLE WORKS	NPDES	NC0003573
STREET 1	22828 NC HIGHWAY 87 WEST	SIC CODE	2821 = Plastics Materials And Resins
CITY		MAJOR / MINOR	M = Major
COUNTY NAME	Bladen	TYPE OF OWNERSHIP	Privately Owned Facility
STATE	NC	ACTIVITY STATUS	Expired
ZIP CODE	283067332	INACTIVE DATE	
REGION	Region 4	TYPE OF PERMIT ISSUED	NPDES Individual Permit
LATITUDE	34.831111	ORIGINAL PERMIT ISSUE DATE	13-MAR-1987
LONGITUDE	-78.823611	PERMIT ISSUED DATE	06-FEB-2012
LAT/LON CODE OF ACCURACY		PERMIT EXPIRED DATE	31-OCT-2016

To: Shell, Karrie-Jo[Shell.Karrie-Jo@epa.gov]
From: Grzyb, Julie
Sent: Fri 2/9/2018 8:30:56 PM
Subject: RE: [External] questions about the NPDES permit for Chemours

Karrie-Jo,
Yes, stormwater is covered under NC0003573. There is no separate stormwater permit.
Julie

From: Shell, Karrie-Jo [mailto:Shell.Karrie-Jo@epa.gov]
Sent: Friday, February 09, 2018 1:09 PM
To: Grzyb, Julie <julie.grzyb@ncdenr.gov>
Subject: [External] questions about the NPDES permit for Chemours

Hi Julie.

Molly is out of the office today, and I am trying to answer a few verify some NPDES permitting information re Chemours.

Does Chemours have a separate NPDES permit (i.e., individual or general permit) for any of its storm water? Based on my understanding, all of the storm water is covered under NC0003573?

Thanks.
Karrie-Jo Robinson-Shell, P.E.
Environmental Engineer
US EPA Region 4
Water Protection Division
61 Forsyth Street
Atlanta, GA 30303
(404) 562-9308

To: Timsina, Gopal[Timsina.Gopal@epa.gov]
From: George, Verne
Sent: Mon 7/30/2018 12:40:52 PM
Subject: test
Chemours - Additional Data and Revised Storm Water Plan
RE: Chemours - New Outfall 002 Data
Chemours - New Outfall 002 Data
Chemours - New Outfall 002 Data
Chemours - Outfall 002 Results Received
Chemours Fayetteville: Additional Site Investigation Report
Chemours - New Outfall 002 Results
Chemours - Additional Outfall Results
Chemours - Additional Outfall 002 Results
FW: Chemours Fayetteville Stormwater Sampling Report
Chemours Fayetteville revised Additional Site Investigation Report
FW: Chemours Fayetteville Stormwater Sampling Report
Chemours - Additional Outfall 002 Data
Chemours - Additional Outfall 002 Results
Chemours - Additional Outfall 002 Results
Chemours - Additional Rainfall Sample Results
Chemours - Additional Outfall 002 Results
Chemours - Additional Outfall 002 Results
Chemours - Additional Rain Sample Results
Chemours - Additional Outfall 002 Results
Chemours - Additional Outfall 002 Results
Chemours - Additional Outfall 002 Results
Chemours - Additional Rainfall Results and Two New Locations
Chemours - Additional Outfall 002 and Rainfall Results
Chemours - Additional Outfall 002 Results
Chemours - Additional Rain Samples
Chemours - Additional Outfall 002 Results
Chemours - Additional Outfall 002 Data
Chemours - Additional Outfall 002 Sample Results
FW: FAY New Preliminary Residential Results - 06-29-18 and 07-11-18
Chemours - Additional Outfall 002 Results

To: Linda Culpepper (linda.culpepper@ncdenr.gov)[linda.culpepper@ncdenr.gov]; Michael Pjetraj[michael.pjetraj@ncdenr.gov]; Allison, Rose[Allison.Rose@epa.gov]; George, Verne[George.Verne@epa.gov]
Cc: Santoro, Thomas[Thomas.Santoro@arnoldporter.com]; Boelter, Karl J[Karl.J.Boelter@chemours.com]; Long, Brian D[Brian.D.Long@chemours.com]; Compton, Christel E[CHRISTEL.E.COMPTON@chemours.com]
From: Johnson, Michael E
Sent: Tue 6/12/2018 7:03:50 PM
Subject: Chemours - Additional Outfall 002 and Rainfall Results
fay prelim results 052118-052818.xlsx

Please see the attached spreadsheet of sampling results received today for HFPO Dimer Acid at Outfall 002 and in rainfall. I am sending you this data instead of Christel Compton because Christel is out on vacation this week.
Mike

Michael E. Johnson, PE
SHE Senior Consultant
Chemours Company – Fayetteville Works
(910) 678-1155

The Chemours Company FC, LLC
22828 NC Highway 87 W
Fayetteville, NC 28306-7332

To: Culpepper, Linda[linda.culpepper@ncdenr.gov]; Allison, Rose[Allison.Rose@epa.gov]; George, Verne[George.Verne@epa.gov]
Cc: Gross, Joel M.[Joel.Gross@apks.com]; Ralph Levene[rmlevene@wlrk.com]; Rumsey, Allison B.[Allison.Rumsey@arnoldporter.com]; Boelter, Karl J[Karl.J.Boelter@chemours.com]; Long, Brian D[Brian.D.Long@chemours.com]
From: Compton, Christel E
Sent: Fri 4/6/2018 7:44:14 PM
Subject: Chemours - Additional Outfall 002 Data

Linda,
Please find additional Outfall 002 data that was received today, April 6, 2018.
Additional Outfall 002 Results
Please find below additional Outfall 002 results analyzed by Test America for HFPO Dimer Acid.

Date Sample Collected (3.5-day Composites)	Results (ppt)
Mar 26, 2018	380
Mar 29, 2018	140

- ∀ On March 24, 2018, the site had 0.43 inches of rain.
- ∀ On March 25, 2018, the site had 0.44 inches of rain.
- ∀ On March 26, 2018, the site had 0.19 inches of rain.
- ∀ On March 27, 2018, the site had 0.02 inches of rain.
- ∀ On March 28, 2018, the site had 0.02 inches of rain.

Thank you –
Christel

Christel Compton
Program Manager
The Chemours Company – Fayetteville Works
(o) 910-678-1213
(m) Personal Phone / Ex. 6

Chemours™

The Chemours Company FC, LLC
22828 NC Highway 87 W
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To: Culpepper, Linda[linda.culpepper@ncdenr.gov]; Allison, Rose[Allison.Rose@epa.gov]; George, Verne[George.Verne@epa.gov]
Cc: Santoro, Thomas[Thomas.Santoro@arnoldporter.com]; Long, Brian D[Brian.D.Long@chemours.com]; Boelter, Karl J[Karl.J.Boelter@chemours.com]
From: Compton, Christel E
Sent: Mon 7/9/2018 9:18:37 PM
Subject: Chemours - Additional Outfall 002 Data

Linda,
Please find additional Outfall 002 data that was received today, July 9, 2018.
Additional Outfall 002 Results
Please find below additional Outfall 002 results analyzed by Test America for HFPO Dimer Acid.

Date Sample Collected (3.5-day Composites)	Results (ppt)
June 11, 2018	52
June 14, 2018	220

- On June 11, 2018, the site had 0.98 inches of rain.
- On June 12, 2018, the site had 0.75 inches of rain.

Thank you –
Christel

Christel Compton
Program Manager
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To: Culpepper, Linda[linda.culpepper@ncdenr.gov]; George, Verne[George.Verne@epa.gov]; Allison, Rose[Allison.Rose@epa.gov]
Cc: Santoro, Thomas[Thomas.Santoro@arnoldporter.com]; Boelter, Karl J[Karl.J.Boelter@chemours.com]
From: Compton, Christel E
Sent: Thur 3/22/2018 9:48:49 PM
Subject: Chemours - Additional Outfall 002 Results

Linda,
Please find additional Outfall 002 data that was received yesterday, March 21, 2018.
Additional Outfall 002 Results
Please find below additional Outfall 002 results analyzed by Test America for HFPO Dimer Acid.

Date Sample Collected (3.5-day Composites)	Results (ppt)
Mar 5, 2018	230 *
Mar 8, 2018	220

*** Please note: The result for March 5, 2018 had a laboratory flag of F1 beside the result. The Test America qualifier F1 indicates the associated matrix spike and/or matrix spike duplicate (MS and/or MSD) Recovery is outside acceptance limits.**

∀ On March 6, 2018, the site had 0.18 inches of rain.

Thank you –
Christel

Christel Compton
Program Manager
The Chemours Company – Fayetteville Works
(o) 910-678-1213
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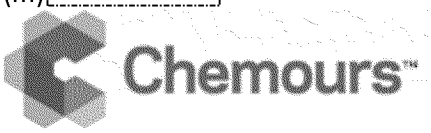

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To: Culpepper, Linda[linda.culpepper@ncdenr.gov]; George, Verne[George.Verne@epa.gov]; Rumsey, Allison B.[Allison.Rumsey@arnoldporter.com]
Cc: Santoro, Thomas[Thomas.Santoro@arnoldporter.com]; Boelter, Karl J[Karl.J.Boelter@chemours.com]; Long, Brian D[Brian.D.Long@chemours.com]
From: Compton, Christel E
Sent: Wed 4/18/2018 6:54:39 PM
Subject: Chemours - Additional Outfall 002 Results

Linda,
Please find additional Outfall 002 data that was received today, April 18, 2018.
Additional Outfall 002 Results
Please find below additional Outfall 002 results analyzed by Test America for HFPO Dimer Acid.

Date Sample Collected (3.5-day Composites)	Results (ppt)
Apr 2, 2018	92

Thank you –
Christel
Christel Compton
Program Manager
The Chemours Company – Fayetteville Works
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To: Culpepper, Linda[linda.culpepper@ncdenr.gov]; Allison, Rose[Allison.Rose@epa.gov]; George, Verne[George.Verne@epa.gov]
Cc: Garon, Kevin P[Kevin.Garon@chemours.com]; Santoro, Thomas[Thomas.Santoro@arnoldporter.com]; Ralph Levene[rmlevene@wlrk.com]; Boelter, Karl J[Karl.J.Boelter@chemours.com]; Long, Brian D[Brian.D.Long@chemours.com]
From: Compton, Christel E
Sent: Tue 5/1/2018 8:12:40 PM
Subject: Chemours - Additional Outfall 002 Results

Linda,

Please find additional Outfall 002 data that was received today, May 1, 2018.

Additional Outfall 002 Results

Please find below additional Outfall 002 results analyzed by Test America for HFPO Dimer Acid. In addition to the rain totals also provided below, it is worthy to note that there were remediation activities associated with the cooling water ditch that may have affected the April 9 composite result (sample collected April 5 – April 9).

Date Sample Collected (3.5-day Composites)	Results (ppt)
Apr 5, 2018	91
Apr 9, 2018	1,300
Apr 12, 2018	120

- ∀ On April 7, 2018, the site had 0.59 inches of rain.
- ∀ On April 8, 2018, the site had 0.6 inches of rain.
- ∀ On April 9, 2018, the site had 0.26 inches of rain.

Thank you –

Christel
Christel Compton
Program Manager
The Chemours Company – Fayetteville Works
(o) 910-678-1213
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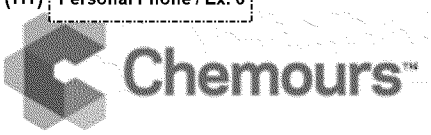

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To: Culpepper, Linda[linda.culpepper@ncdenr.gov]; Allison, Rose[Allison.Rose@epa.gov]; George, Verne[George.Verne@epa.gov]
Cc: Garon, Kevin P[Kevin.Garon@chemours.com]; Santoro, Thomas[Thomas.Santoro@arnoldporter.com]; Boelter, Karl J[Karl.J.Boelter@chemours.com]; Long, Brian D[Brian.D.Long@chemours.com]; Ralph Levene[rmlevene@wlrk.com]
From: Compton, Christel E
Sent: Mon 5/7/2018 3:01:37 PM
Subject: Chemours - Additional Outfall 002 Results

Linda,
Please find additional Outfall 002 data that was received today, May 7, 2018.
Additional Outfall 002 Results
Please find below additional Outfall 002 results analyzed by Test America for HFPO Dimer Acid.

Date Sample Collected (3.5-day Composites)	Results (ppt)
Apr 16, 2018	680
Apr 19, 2018	46

∀ On April 16, 2018, the site had 0.92 inches of rain.

Thank you –
Christel

Christel Compton
Program Manager
The Chemours Company – Fayetteville Works
(o) 910-678-1213
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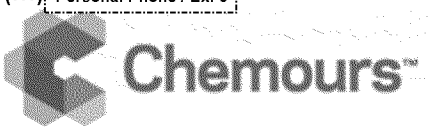

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To: Culpepper, Linda[linda.culpepper@ncdenr.gov]; Allison, Rose[Allison.Rose@epa.gov]; George, Verne[George.Verne@epa.gov]
Cc: Santoro, Thomas[Thomas.Santoro@arnoldporter.com]; Boelter, Karl J[Karl.J.Boelter@chemours.com]; Long, Brian D[Brian.D.Long@chemours.com]
From: Compton, Christel E
Sent: Tue 5/15/2018 3:56:26 PM
Subject: Chemours - Additional Outfall 002 Results

Linda,
Please find additional Outfall 002 data that was received today, May 15, 2018.
Additional Outfall 002 Results
Please find below additional Outfall 002 results analyzed by Test America for HFPO Dimer Acid.

Date Sample Collected (3.5-day Composites)	Results (ppt)
Apr 23, 2018	190
Apr 26, 2018	1,100

- On April 23, 2018, the site had 0.14 inches of rain.
- On April 24, 2018, the site had 1.26 inches of rain.

Thank you –
Christel

Christel Compton
Program Manager
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Cc: Santoro, Thomas[Thomas.Santoro@arnoldporter.com]; Boelter, Karl J[Karl.J.Boelter@chemours.com]; Long, Brian D[Brian.D.Long@chemours.com]; Compton, Christel E[CHRISTEL.E.COMPTON@chemours.com]
From: Compton, Christel E
Sent: Mon 5/21/2018 3:30:16 PM
Subject: Chemours - Additional Outfall 002 Results

Linda,
Please find additional Outfall 002 data that was received today, May 21, 2018.
Additional Outfall 002 Results
Please find below additional Outfall 002 results analyzed by Test America for HFPO Dimer Acid.

Date Sample Collected (3.5-day Composites)	Results (ppt)
Apr 30, 2018	180
May 3, 2018	90

∀ On April 27, 2018, the site had 0.15 inches of rain.

Thank you –
Christel

Christel Compton
Program Manager
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Cc: Santoro, Thomas[Thomas.Santoro@arnoldporter.com]; Boelter, Karl J[Karl.J.Boelter@chemours.com]; Long, Brian D[Brian.D.Long@chemours.com]
From: Compton, Christel E
Sent: Wed 5/30/2018 8:20:16 PM
Subject: Chemours - Additional Outfall 002 Results

Linda,
Please find additional Outfall 002 data that was received today, May 30, 2018.
Additional Outfall 002 Results
Please find below additional Outfall 002 results analyzed by Test America for HFPO Dimer Acid.

Date Sample Collected (3.5-day Composites)	Results (ppt)
May 7, 2018	81
May 10, 2018	68

Thank you –
Christel

Christel Compton
Program Manager
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Cc: Thomas.Santoro@arnoldporter.com[Thomas.Santoro@arnoldporter.com]; Boelter, Karl J[Karl.J.Boelter@chemours.com]; Long, Brian D[Brian.D.Long@chemours.com]
From: Compton, Christel E
Sent: Tue 6/5/2018 7:02:29 PM
Subject: Chemours - Additional Outfall 002 Results

Linda,
Please find additional Outfall 002 data that was received today, June 5, 2018.
Additional Outfall 002 Results
Please find below additional Outfall 002 results analyzed by Test America for HFPO Dimer Acid.

Date Sample Collected (3.5-day Composites)	Results (ppt)
May 14, 2018	100
May 17, 2018	110

∀ On May 16, 2018, the site had 0.18 inches of rain.

Thank you –
Christel

Christel Compton
Program Manager
The Chemours Company – Fayetteville Works
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Cc: Santoro, Thomas[Thomas.Santoro@arnoldporter.com]; Boelter, Karl J[Karl.J.Boelter@chemours.com]; Long, Brian D[Brian.D.Long@chemours.com]
From: Compton, Christel E
Sent: Mon 6/18/2018 7:58:05 PM
Subject: Chemours - Additional Outfall 002 Results

Linda,
Please find additional Outfall 002 data that was received today, June 18, 2018.
Additional Outfall 002 Results
Please find below additional Outfall 002 results analyzed by Test America for HFPO Dimer Acid.

Date Sample Collected (3.5-day Composites)	Results (ppt)
May 29, 2018	290
May 31, 2018	120
June 4, 2018 - 1	66
June 4, 2018 - 2	68
June 4, 2018 - 3	82
June 7, 2018	59

- ∀ On May 28, 2018, the site had 0.55 inches of rain.
- ∀ On May 29, 2018, the site had 0.48 inches of rain.

Thank you –
Christel

Christel Compton
Program Manager
The Chemours Company – Fayetteville Works
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Cc: Thomas.Santoro@arnoldporter.com[Thomas.Santoro@arnoldporter.com]; Long, Brian D[Brian.D.Long@chemours.com]; Boelter, Karl J[Karl.J.Boelter@chemours.com]; Compton, Christel E[CHRISTEL.E.COMPTON@chemours.com]
From: Compton, Christel E
Sent: Thur 7/5/2018 3:41:39 PM
Subject: Chemours - Additional Outfall 002 Results

Linda,
Please find additional Outfall 002 data that was received today, July 5, 2018.
Additional Outfall 002 Results
Please find below additional Outfall 002 results analyzed by Test America for HFPO Dimer Acid.

Date Sample Collected (3.5-day Composites)	Results (ppt)
June 18, 2018	76
June 21, 2018	120

- ∀ On June 18, 2018, the site had 0.39 inches of rain.
- ∀ On June 19, 2018, the site had 0.39 inches of rain.

Thank you –
Christel

Christel Compton
Program Manager
The Chemours Company – Fayetteville Works
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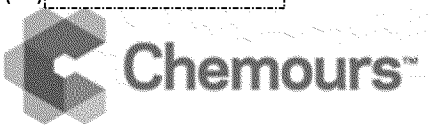

The Chemours Company FC, LLC
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To: Culpepper, Linda[linda.culpepper@ncdenr.gov]; George, Verne[George.Verne@epa.gov]; Allison, Rose[Allison.Rose@epa.gov]
Cc: Santoro, Thomas[Thomas.Santoro@arnoldporter.com]; Long, Brian D[Brian.D.Long@chemours.com]; Boelter, Karl J[Karl.J.Boelter@chemours.com]
From: Compton, Christel E
Sent: Mon 7/23/2018 8:48:32 PM
Subject: Chemours - Additional Outfall 002 Results

Linda,
Please find additional Outfall 002 data that was received today, July 23, 2018.
Additional Outfall 002 Results
Please find below additional Outfall 002 results analyzed by Test America for HFPO Dimer Acid.

Date Sample Collected (3.5-day Composites)	Results (ppt)
July 2, 2018	41
July 5, 2018	38

There were no rain events during this collection period.
Thank you –
Christel

Christel Compton
Program Manager
The Chemours Company – Fayetteville Works
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Cc: Santoro, Thomas[Thomas.Santoro@arnoldporter.com]; Long, Brian D[Brian.D.Long@chemours.com]; Boelter, Karl J[Karl.J.Boelter@chemours.com]
From: Compton, Christel E
Sent: Fri 7/20/2018 8:43:06 PM
Subject: Chemours - Additional Outfall 002 Sample Results

Linda,
Please find additional Outfall 002 data that was received today, July 20, 2018.
Additional Outfall 002 Results
Please find below additional Outfall 002 results analyzed by Test America for HFPO Dimer Acid.

Date Sample Collected (3.5-day Composites)	Results (ppt)
June 25, 2018	48
June 28, 2018	150

- ∀ On June 24, 2018, the site had 0.03 inches of rain.
- ∀ On June 25, 2018, the site had 0.49 inches of rain.
- ∀ On June 26, 2018, the site had 0.89 inches of rain.
- ∀ On June 27, 2018, the site had 0.89 inches of rain.

Thank you –
Christel

Christel Compton
Program Manager
The Chemours Company – Fayetteville Works
(o) 910-678-1213
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Chemours™

The Chemours Company FC, LLC
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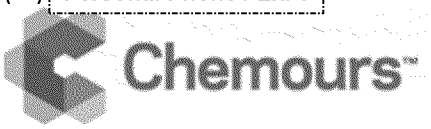
To: Culpepper, Linda[linda.culpepper@ncdenr.gov]; George, Verne[George.Verne@epa.gov]; Allison, Rose[Allison.Rose@epa.gov]
Cc: Santoro, Thomas[Thomas.Santoro@arnoldporter.com]; Boelter, Karl J[Karl.J.Boelter@chemours.com]
From: Compton, Christel E
Sent: Mon 3/19/2018 5:38:06 PM
Subject: Chemours - Additional Outfall Results

Linda,
Please find additional Outfall 002 data that was received today, March 13, 2018.
Additional Outfall 002 Results
Please find below additional Outfall 002 results analyzed by Test America for HFPO Dimer Acid.

Date Sample Collected (3.5-day Composites)	Results (ppt)
Feb 26, 2018	140
Mar 1, 2018	450

On February 26, 2018, the site had 0.18 inches of rain.
On March 1, 2018, the site had 0.7 inches of rain.
Thank you –
Christel

Christel Compton
Program Manager
The Chemours Company – Fayetteville Works
(o) 910-678-1213
(m) Personal Phone / Ex. 6



The Chemours Company FC, LLC
22828 NC Highway 87 W
Fayetteville, NC 28306-7332

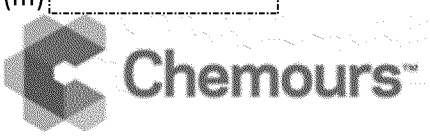
To: Michael Pjetraj[michael.pjetraj@ncdenr.gov]
Cc: Thomas.Santoro@arnoldporter.com[Thomas.Santoro@arnoldporter.com]; Allison, Rose[Allison.Rose@epa.gov]; George, Verne[George.Verne@epa.gov]; Long, Brian D[Brian.D.Long@chemours.com]; Boelter, Karl J[Karl.J.Boelter@chemours.com]
From: Compton, Christel E
Sent: Mon 7/2/2018 6:27:54 PM
Subject: Chemours - Additional Rain Samples

Michael –
We have received additional rain sample results today, July 2, 2018. The results for 5/24/18 and 5/28/18 were previously sent by Mike Johnson. I am repeating here due to format and consistency on how rain data had previously been sent to you.
A = west of River Water Intake, which is located NE of the operating areas;
B = solar field, which is located SE of the operating areas;
C = south gate, which is located south of the operating areas and the furthest point from the operating areas.

Date- sample collection	Rain (ppt)	Location
5/24/2018	< 10	River Intake -A
5/24/2018	< 10	Solar Field -B
5/24/2018	< 10	South Gate - C
5/28/2018	< 10	River Intake -A
5/28/2018	20	Solar Field -B
5/28/2018	< 10	South Gate - C
6/12/2018	< 10	River Intake -A
6/12/2018	< 10	Solar Field -B
6/12/2018	< 10	South Gate - C

Please let me know if you have any questions. I will send production data under separate CBI cover.
Thanks –
Christel

Christel Compton
Program Manager
The Chemours Company – Fayetteville Works
(o) 910-678-1213
(m) Personal Phone / Ex. 6



The Chemours Company FC, LLC
22828 NC Highway 87 W
Fayetteville, NC 28306-7332

Francais Italiano Deutsch Portuges Espanol Japanese Chinese Korean

https://www.chemours.com/Chemours_Home/en_US/email_disclaimer.html

To: Michael Pjetraj[michael.pjetraj@ncdenr.gov]
Cc: George, Verne[George.Verne@epa.gov]; Allison, Rose[Allison.Rose@epa.gov]; Thomas.Santoro@arnoldporter.com[Thomas.Santoro@arnoldporter.com]; Boelter, Karl J[Karl.J.Boelter@chemours.com]; Long, Brian D[Brian.D.Long@chemours.com]
From: Compton, Christel E
Sent: Wed 6/6/2018 8:24:45 PM
Subject: Chemours - Additional Rainfall Results and Two New Locations

Michael –
We have received additional rain sample results today, June 6, 2018. This is the first set that includes the two additional locations we added, B and C:
A = west of River Water Intake, which is located NE of the operating areas;
B = solar field, which is located SE of the operating areas;
C = south gate, which is located south of the operating areas and the furthest point from the operating areas.

Date- sample collection	Rain (ppt)	Location
5/17/2018	100	River Intake - A
5/17/2018	< 10	Solar Field -B
5/17/2018	< 10	South Gate - C
5/19/2018	520	River Intake -A
5/19/2018	58	Solar Field -B
5/19/2018	73	South Gate - C

Under separate CBI cover, I will send you the operations that were running at the time of sample collection for these samples.
Thanks –
Christel

Christel Compton
Program Manager
The Chemours Company – Fayetteville Works
(o) 910-678-1213
(m) Personal Phone / Ex. 6

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parties.

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To: Michael Pjetraj[michael.pjetraj@ncdenr.gov]; Allison, Rose[Allison.Rose@epa.gov]; George, Verne[George.Verne@epa.gov]
Cc: Santoro, Thomas[Thomas.Santoro@arnoldporter.com]
From: Compton, Christel E
Sent: Tue 5/1/2018 8:18:50 PM
Subject: Chemours - Additional Rainfall Sample Results

Michael –
We have received additional rain sample results, collected at the same location as previous rain samples (west of the River Water pump house):

Sample Collected	Result (ug/l)
4/7/2018	30
4/8/2018	190
4/15/2018	410

Under separate CBI cover, I will send you the operations that were running at the time of sample collection for these samples.
Thanks –
Christel

Christel Compton
Program Manager
The Chemours Company – Fayetteville Works
(o) 910-678-1213
(m) Personal Phone / Ex. 6

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The Chemours Company FC, LLC
22828 NC Highway 87 W
Fayetteville, NC 28306-7332

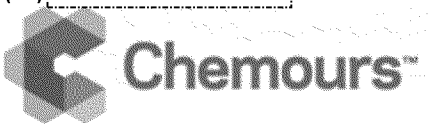
To: Culpepper, Linda[linda.culpepper@ncdenr.gov]
Cc: George, Verne[George.Verne@epa.gov]; Allison, Rose[Allison.Rose@epa.gov]; Compton, Christel E[CHRISTEL.E.COMPTON@chemours.com]
From: Compton, Christel E
Sent: Wed 2/7/2018 2:01:20 AM
Subject: Chemours - New Outfall 002 Data

Linda,
Please find additional Outfall 002 data that was received today, February 6, 2018.
Additional Outfall 002 Results
Please find below additional Outfall 002 results analyzed by Test America for HFPO Dimer Acid.

Date Sample Collected (3.5-day Composites)	Results (ppt)
Jan 18, 2018	360
Jan 22, 2018	1,500
Jan 25, 2018	1,300

Thank you –
Christel

Christel Compton
Program Manager
The Chemours Company – Fayetteville Works
(o) 910-678-1213
(m) Personal Phone / Ex. 6



The Chemours Company FC, LLC
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Fayetteville, NC 28306-7332

To: Culpepper, Linda[linda.culpepper@ncdenr.gov]; George, Verne[George.Verne@epa.gov]; Allison, Rose[Allison.Rose@epa.gov]
From: Compton, Christel E
Sent: Wed 2/14/2018 5:25:25 PM
Subject: Chemours - New Outfall 002 Data

Linda,
Please find additional Outfall 002 data that was received today, February 14, 2018.
Additional Outfall 002 Results
Please find below additional Outfall 002 results analyzed by Test America for HFPO Dimer Acid.

Date Sample Collected (3.5-day Composites)	Results (ppt)
Jan 29, 2018	950
Feb 1, 2018	410

The Site had a rainfall event on January 28, 2018 of 1.2 Inches.
Thank you –
Christel

Christel Compton
Program Manager
The Chemours Company – Fayetteville Works
(o) 910-678-1213
(m) Personal Phone / Ex. 6

Chemours™

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To: Culpepper, Linda[linda.culpepper@ncdenr.gov]; George, Verne[George.Verne@epa.gov]; Allison, Rose[Allison.Rose@epa.gov]
Cc: Compton, Christel E[CHRISTEL.E.COMPTON@chemours.com]
From: Compton, Christel E
Sent: Thur 3/8/2018 10:19:31 PM
Subject: Chemours - New Outfall 002 Results

Linda,
Please find additional Outfall 002 data that was received today, March 8, 2018.
Additional Outfall 002 Results
Please find below additional Outfall 002 results analyzed by Test America for HFPO Dimer Acid.

Date Sample Collected (3.5-day Composites)	Results (ppt)
Feb 19, 2018	87
Feb 22, 2018	83

Thank you –
Christel

Christel Compton
Program Manager
The Chemours Company – Fayetteville Works
(o) 910-678-1213
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Fayetteville, NC 28306-7332

To: Culpepper, Linda[linda.culpepper@ncdenr.gov]
Cc: George, Verne[George.Verne@epa.gov]; Allison, Rose[Allison.Rose@epa.gov]
From: Compton, Christel E
Sent: Tue 2/20/2018 5:05:57 PM
Subject: Chemours - Outfall 002 Results Received

Linda,
Please find additional Outfall 002 data that was received today, February 20, 2018.
Additional Outfall 002 Results
Please find below additional Outfall 002 results analyzed by Test America for HFPO Dimer Acid.

Date Sample Collected (3.5-day Composites)	Results (ppt)
Feb 5, 2018	610
Feb 8, 2018	340

The Site had a rainfall event on February 4, 2018 totaling 1.0 inch.
Thank you –
Christel

Christel Compton
Program Manager
The Chemours Company – Fayetteville Works
(o) 910-678-1213
(m) Personal Phone / Ex. 6

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The Chemours Company FC, LLC
22828 NC Highway 87 W
Fayetteville, NC 28306-7332

To: Ghiold, Joe[joe.ghiold@ncdenr.gov]; Scott, Michael[michael.scott@ncdenr.gov]; Bud.mccarty@ncdenr.gov[Bud.mccarty@ncdenr.gov]; Woosley, Julie[julie.woosley@ncdenr.gov]; Mort, Sandra L[sandy.mort@ncdenr.gov]
Cc: Allison, Rose[Allison.Rose@epa.gov]; George, Verne[George.Verne@epa.gov]; Rumsey, Allison B.[Allison.Rumsey@apks.com]; Shoemaker, Stephen H[STEPHEN.H.SHOEMAKER@chemours.com]; Compton, Christel E[CHRISTEL.E.COMPTON@chemours.com]; Ovbey, Tracy (Tracy.Ovbey@parsons.com)[Tracy.Ovbey@parsons.com]
From: Garon, Kevin P
Sent: Fri 3/30/2018 1:01:23 AM
Subject: Chemours Fayetteville revised Additional Site Investigation Report
Fayetteville Additional Investigation Report - revised - no Lab Reports.pdf
Fayetteville Additional Site Investigation Report 3-29-2018 Cover Letter.pdf

Dr. Ghiold,
Attached please find the revised Chemours Fayetteville "Additional Site Investigation Report" and a cover letter. The report was originally submitted to NCDEQ on January 31, 2018. This report was revised to include additional figures and analytical data reports as well as to address comments sent by you via e-mail on February 9, 2018 and to address verbal comments from you on March 23, 2018. Due to their large size, the two laboratory data packages (Appendix A and Appendix D) are not included in this attached document. Hard copies are being shipped to you by our consultant, Parsons, and will include an electronic disc or flash drive that contains both complete laboratory reports.
Please call or e-mail with questions or comments.
Respectfully submitted,
Kevin

Kevin P. Garon

Principal Project Director

Chemours Corporate Remediation Group

704-560-6435

Kevin.Garon@Chemours.com

The Chemours Company

To: Allison, Rose[Allison.Rose@epa.gov]; George, Verne[George.Verne@epa.gov]
From: Garon, Kevin P
Sent: Fri 2/23/2018 3:41:20 AM
Subject: Chemours Fayetteville: Additional Site Investigation Report
Chemours Fayetteville Additional Site Investigation Report - NCD047368642-R1.pdf

Ms. Rose and Mr. Verne,
Attached please find a copy of our cover letter and a PDF version of the *Additional Site Investigation Report* for the Chemours Fayetteville Works which Chemours recently provided to the *North Carolina Department of Environmental Quality.*
Respectfully submitted,
Kevin

Kevin P. Garon

Principal Project Director

Chemours Corporate Remediation Group

704-560-6435

Kevin.Garon@Chemours.com

The Chemours Company

LinkedIn | Twitter | Chemours.com

From: Garon, Kevin P
Sent: Wednesday, January 31, 2018 5:06 PM
To: Ghiold, Joe
Cc: 'Mccarty, Bud' ; 'Scott, Michael' ; Shoemaker, Stephen H ; eric.rey@apks.com
Subject: Additional Site Investigation Report
Importance: High

Dr. Ghiold,
Attached please find a cover letter and a PDF version of the *Additional Site Investigation Report* for the Chemours Fayetteville Works. This version of the report contains the text, tables and figures. Due to the size of the laboratory reports, they are being sent to you on CD with two additional hard copies of this report.
Please know that we are continuing to gather more information and data on the site and as we do, we will share that information with NCDEQ and continue to work collaboratively. As we continue to move through the investigation, corrective measures review and finally remedy selection process, we are also working in parallel to identify any interim responses that could be quickly implemented, with special attention toward those which could potentially have positive impact on the continued reductions of PFAS concentrations at outfall 002.
Please call or e-mail me with any questions or comments.
Respectfully submitted,
Kevin

Kevin P. Garon

Principal Project Director

Chemours Corporate Remediation Group

704-560-6435

Kevin.Garon@Chemours.com

The Chemours Company

LinkedIn | Twitter | Chemours.com

To: Allison, Rose[Allison.Rose@epa.gov]; George, Verne[George.Verne@epa.gov]
Cc: Rumsey, Allison B.[Allison.Rumsey@apks.com]
From: Garon, Kevin P
Sent: Thur 3/29/2018 1:50:26 PM
Subject: FW: Chemours Fayetteville Stormwater Sampling Report
Fayetteville Works Stormwater Sampling Report - 2018-03-29 - wo Lab Reports.pdf

Ms. Rose and Mr. Verne,
My apologies for not copying you on this report that I sent out about a half hour ago. Here is the Chemours Fayetteville Stormwater Sampling Report.
Thanks, Kevin

From: Garon, Kevin P
Sent: Thursday, March 29, 2018 9:12 AM
To: Ghiold, Joe
Cc: Scott, Michael ; 'Mccarty, Bud' ; Mort, Sandra L ; Woosley, Julie ; Shoemaker, Stephen H ; Compton, Christel E ; Rumsey, Allison B.
Subject: Chemours Fayetteville Stormwater Sampling Report
Dr. Ghiold,
Please find attached a PDF copy submission of the Stormwater Sampling Report for the Chemours Fayetteville Works. Due to the size of the file, this electronic submittal does not include the full data analysis report (Appendix C). Geosyntec, the firm authoring this report, is sending a printed and bound report copy to your address. This printed copy will include a disc or USB memory stick with a digital copy of the report that which will include the full laboratory reports (all of Appendix C).
Respectfully submitted,
Kevin

Kevin P. Garon

Principal Project Director

Chemours Corporate Remediation Group

704-560-6435

Kevin.Garon@Chemours.com

The Chemours Company

To: R4 Chemours[R4_Chemours@epa.gov]
Cc: Mitchell, Ken[Mitchell.Ken@epa.gov]
From: Mitchell, Ken
Sent: Fri 3/30/2018 5:11:31 PM
Subject: FW: Chemours Fayetteville Stormwater Sampling Report
Fayetteville Works Stormwater Sampling Report - 2018-03-29 - wo Lab Reports.pdf

fyi

Kenneth L. Mitchell, Ph.D. | Special Assistant to the Director |
Air, Pesticides, and Toxics Management Division
U.S. Environmental Protection Agency | 61 Forsyth Street, SW | Atlanta, GA 30303
Voice: 404-562-9065 | Fax: 404-562-9066 | Email: mitchell.ken@epa.gov

From: George, Verne
Sent: Friday, March 30, 2018 12:47 PM
To: Kemker, Carol ; Mitchell, Ken ; Timsina, Gopal ; Bookman, Robert ; Toney, Anthony
Subject: FW: Chemours Fayetteville Stormwater Sampling Report
FYI

From: Garon, Kevin P [mailto:Kevin.Garon@chemours.com]
Sent: Thursday, March 29, 2018 9:50 AM
To: Allison, Rose <Allison.Rose@epa.gov>; George, Verne <George.Verne@epa.gov>
Cc: Rumsey, Allison B. <Allison.Rumsey@apks.com>
Subject: FW: Chemours Fayetteville Stormwater Sampling Report
Ms. Rose and Mr. Verne,
My apologies for not copying you on this report that I sent out about a half hour ago. Here is the Chemours Fayetteville Stormwater Sampling Report.
Thanks, Kevin

From: Garon, Kevin P
Sent: Thursday, March 29, 2018 9:12 AM
To: Ghiold, Joe <joe.ghiold@ncdenr.gov>
Cc: Scott, Michael <michael.scott@ncdenr.gov>; 'Mccarty, Bud' <bud.mccarty@ncdenr.gov>; Mort, Sandra L <sandy.mort@ncdenr.gov>; Woosley, Julie <julie.woosley@ncdenr.gov>; Shoemaker, Stephen H <STEPHEN.H.SHOEMAKER@chemours.com>; Compton, Christel E <CHRISTEL.E.COMPTON@chemours.com>; Rumsey, Allison B. <Allison.Rumsey@apks.com>
Subject: Chemours Fayetteville Stormwater Sampling Report
Dr. Ghiold,
Please find attached a PDF copy submission of the Stormwater Sampling Report for the Chemours Fayetteville Works. Due to the size of the file, this electronic submittal does not include the full data analysis report (Appendix C). Geosyntec, the firm authoring this report, is sending a printed and bound report copy to your address. This printed copy will include a disc or USB memory stick with a digital copy of the report that which will include the full laboratory reports (all of Appendix C).
Respectfully submitted,
Kevin

Kevin P. Garon
Principal Project Director
Chemours Corporate Remediation Group
704-560-6435
Kevin.Garon@Chemours.com
The Chemours Company

To: Scott, Michael[michael.scott@ncdenr.gov]; Holman, Sheila[sheila.holman@ncdenr.gov]; George, Verne[George.Verne@epa.gov]; Allison, Rose[Allison.Rose@epa.gov]; Ghiold, Joe[joe.ghiold@ncdenr.gov]
Cc: Santoro, Thomas[Thomas.Santoro@arnoldporter.com]; Garon, Kevin P[Kevin.Garon@chemours.com]; Long, Brian D[Brian.D.Long@chemours.com]; Boelter, Karl J[Karl.J.Boelter@chemours.com]
From: Compton, Christel E
Sent: Mon 7/23/2018 1:29:11 PM
Subject: FW: FAY New Preliminary Residential Results - 06-29-18 and 07-11-18
Fayetteville Phase 4 - 07-23-2018.xlsx

Michael,
Please see attached list of new contact information (samples collected 6/29/18 and 7/11/18, received today, 7/23/18). There were no results that exceeded 140 ppt. (Note: Personal Matters / Ex. 6 with a result of 120 ng/L, was sampled because the State result was 180 ng/L back on 5/1/2018).
Please note:

1. Result is part of Phase 4 sampling.
2. No result is from wells that are part of the Quarterly Testing of wells between 100 – 139 ppt.
3. There are no shared wells in this group.

Thank you,
Christel

Christel Compton
Program Manager
The Chemours Company – Fayetteville Works
(o) 910-678-1213
(m) Personal Phone / Ex. 6

Chemours™

The Chemours Company FC, LLC
22828 NC Highway 87 W
Fayetteville, NC 28306-7332

From: Liddle, Robert [mailto:Robert.Liddle@parsons.com]
Sent: Monday, July 23, 2018 9:19 AM
To: Garon, Kevin P ; Compton, Christel E ; Vargas, Sonya A
Cc: Ovbey, Tracy ; Kenneth Stuart
Subject: FAY New Preliminary Residential Results - 06-29-18 and 07-11-18
Kevin,
See attached list of contact info (additional new Residential sample collected 06-29-2018 and 07-11-2018).
This spreadsheet includes new Residential results.
There were no results >= 140 ng/L (Note: Personal Matters / Ex. 6 with a result of 120 ng/L, was sampled because the State result was 180 ng/L back on 5/1/2018).
None of the residences share their well with neighbors.
Please let us know if you need any additional information.
Thank you,

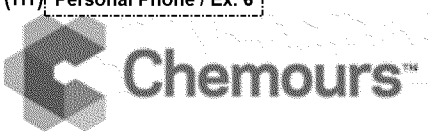
Robert Liddle, PG
Scientific Manager - Environmental
Parsons
2200 West Loop South
Suite 200
Houston, TX 77027
Cell: Personal Phone / Ex. 6
FAX: 713.871.7171
Robert.Liddle@parsons.com
www.parsons.com

To: Culpepper, Linda[linda.culpepper@ncdenr.gov]
Cc: George, Verne[George.Verne@epa.gov]; Allison, Rose[Allison.Rose@epa.gov]; Compton, Christel E[CHRISTEL.E.COMPTON@chemours.com]
From: Compton, Christel E
Sent: Wed 2/7/2018 11:00:56 PM
Subject: RE: Chemours - New Outfall 002 Data

Linda –
I inadvertently left off the following from my email from yesterday:

Date Sample Collected (3.5-day Composites)	Results (ppt)
Jan 16, 2018	370

Thank you –
Christel
Christel Compton
Program Manager
The Chemours Company – Fayetteville Works
(o) 910-678-1213
(m) Personal Phone / Ex. 6



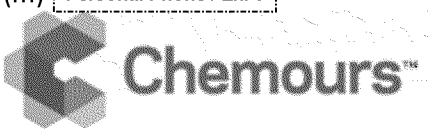
The Chemours Company FC, LLC
22828 NC Highway 87 W
Fayetteville, NC 28306-7332

From: Compton, Christel E
Sent: Tuesday, February 06, 2018 9:01 PM
To: 'Culpepper, Linda'
Cc: 'George.verne@Epa.gov' ; 'Allison.rose@Epa.gov' ; Compton, Christel E
Subject: Chemours - New Outfall 002 Data

Linda,
Please find additional Outfall 002 data that was received today, February 6, 2018.
Additional Outfall 002 Results
Please find below additional Outfall 002 results analyzed by Test America for HFPO Dimer Acid.

Date Sample Collected (3.5-day Composites)	Results (ppt)
Jan 18, 2018	360
Jan 22, 2018	1,500
Jan 25, 2018	1,300

Thank you –
Christel
Christel Compton
Program Manager
The Chemours Company – Fayetteville Works
(o) 910-678-1213
(m) Personal Phone / Ex. 6



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